United States
Department of
Agriculture

Food Safety and
Inspection Service

Hosted by:
Texas A&M
University

Proceedings of the World Congress on Meat and Poultry Inspection – 1993

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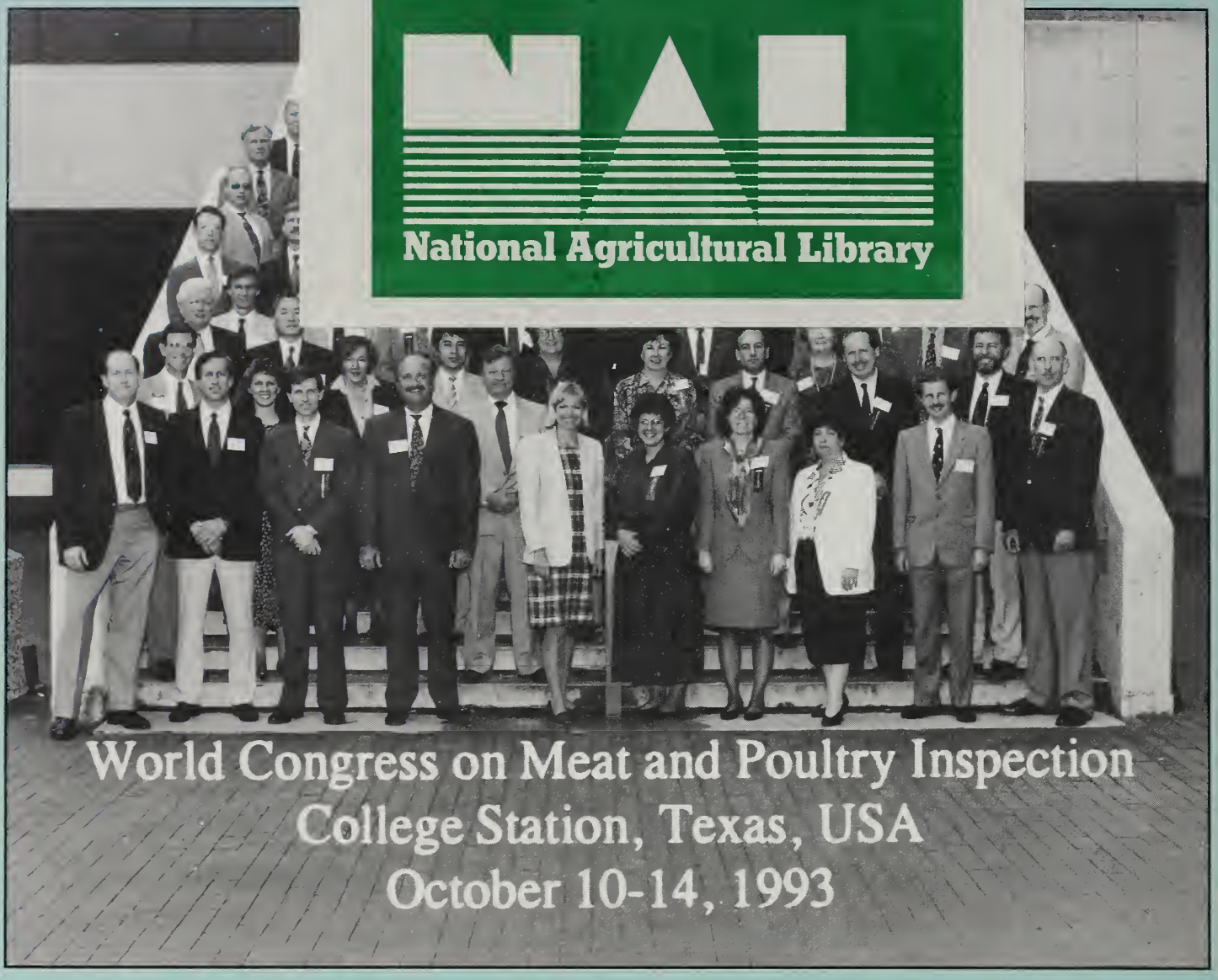

Left to Right. Front Row: Tom Feltmate, Hector Lazaneo, Gary Acuff, Jeffrey Savell, Laurian Unnevehr, Patricia Brickerd, Anne Marie McNamara, Priscilla Levine, James Egan, John Prucha. Second Row: Jimmy Keeton, Beth Lautner, Lee Christensen, Robert Biddle, Barry Marshall. Third Row: Edith Kennard, Dae-Jin Kang, Darlene Riden, Richard Carnevale. Fourth Row: Keith Baker, Ok-Kyung Kim, Anne MacKenzie, Jeffrey Brown, Rosemary Mucklow, Neil Armitage, Kenneth McDougall. Fifth Row: Peter Hewson, Gary Smith, Marvin Norcross, Donald Luchsinger, Tari Kindred, G. A. Mitchell, Reinhard Reimer, C. C. J. M. Van Der Meijs. Sixth Row: William Dennis, William James, Lonnie King, Maurice Morissette, Ian Sutherland, Barry Shay, Daniel Lazenby, Jorgen Baltzer, Graham Clarke, Terry Ryan. Seventh Row: Charles Williams, William Dubbert, Rhonda Nally, Wilson Horne, Gerry Gillespie, James Murray, Paul Vanderlinde, John Nicholson, Richard Forsythe. Eighth Row: Robert Brewer, Douglas Berndt. Ninth Row: Robert Brown, André Gravel. Tenth Row: Richard McCapes, Ken Byrd, Arthur Miller, James Marion, Barnabas Sas, Brian Hogben, G. A. Lam, James Denton. Top Row: Jack Leighty, Ramon Cardinal, Martin Terry, Andrew McKenzie, Stephen Carroll, Steve Hathaway, Jack Haslam.

Not pictured: Tony Brown, Russell Cross, Jim Hodges, Walter Juliff, Rhonda Miller, Ellen Morton, Bennie Osburn, and Leon Russell.

World Congress on Meat and Poultry Inspection

October 10-14, 1993

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Preface

The conviction is widely shared among scientists, regulatory authorities, and informed members of the general public that the responsibility for assuring food safety cannot be lodged in any single link in the production, distribution, and consumption chain. Comprehensive safety assurance is to be achieved by applying risk analysis concepts in preharvest and postharvest production stages, including safeguards against chemical and microbiological hazards. Integrated systems approaches incorporating Hazard Analysis and Critical Control Points (HACCP) must be taken to reduce and control hazards associated with meat and poultry products and other foods. Agreement on applying these systems must be reached, consistent with the principles of harmonization, in the interests of both food safety and international commerce. Cooperation and communication among producers, processors, distributors, consumers, and regulatory authorities—and the education of all food handlers—are essential in raising the level of confidence in the systems for safety assurance. None of these groups operates in a vacuum; all must move forward together.

Such views were espoused by the representatives of eleven countries and the European Commission who gathered 11-14 October 1993 in College Station, Texas, for the World Congress on Meat and Poultry Inspection. The World Congress was jointly hosted by the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture, and Texas A&M University. Those attending included regulatory officials, government and academic scientists, officials of trade and professional associations, consumer and public interest group representatives, and members of the press. The 1993 Congress differed from previous meetings in its program concept. The topic for each working session concerned a phase of the meat and poultry production, processing, and consumption cycle, and the inspection and food safety problems arising in each phase.

Specific approaches to be taken in the areas addressed by the World Congress were suggested at its outset by the authors of six overview papers that had been commissioned by the Congress organizers. The organizers had submitted lists of discussion questions to the authors, asking to them to cover the questions in their papers. These authors—distinguished scientists and regulatory officials—and their respective topics were: Dr. André Gravel of Agriculture Canada—Traditional Postmortem Inspection; Dr. Jorgen Baltzer, head of meat inspection for the Danish Agriculture Ministry—Preharvest Pathogen Reduction; Dr. Steve Hathaway of the New Zealand Ministry of Agriculture and Fisheries—Risk Analysis; Dr. C. C. J. M. van der Meijs of the Netherlands Ministry of Agriculture, Nature Management, and Fisheries—Residue Control; Drs. Robert Biddle, Barry Shay, and Peter Miller of Australia—Postharvest Pathogen Reduction; and Dr. Gary R. Acuff of Texas A&M University—Microbiological Criteria.

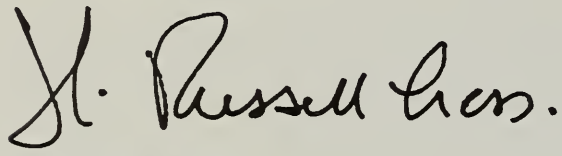
The overview papers, provided as reference material at the end of this document, summarize current thinking on these topics and were springboards to discussion in the "breakout" sessions, or working groups, formed by World Congress participants. Discussions in each group were facilitated by senior USDA officials who were, respectively: Dr. William O. James, FSIS, Traditional Postmortem Inspection; Dr. Lonnie J. King, Animal and Plant Health Inspection Service, Preharvest Pathogen Reduction; Dr. Richard A. Carnevale, FSIS, Risk Analysis; Dr. Marvin A. Norcross, FSIS, Residue Control; Dr. John C. Prucha, FSIS, Postharvest Pathogen Reduction; and Dr. Ann Marie McNamara, FSIS, Microbiological Criteria.

Each working group produced a consensus paper elaborating on the themes and conclusions presented in an overview paper. The consensus papers were presented at a plenary session on the last day of the World Congress and were revised in the light of comments received.

The consensus papers are presented here for the consideration of an international audience. Included with the papers are a list of all World Congress participants and lists of participants in each breakout group. The papers reflect the views of citizens and officials of trading nations who have strong professional interests and qualifications

in the subjects discussed. They do not constitute official agreements or recommendations, but it is expected that policy makers, opinion leaders, and industry executives will recognize their merit and the seriousness with which the ideas in them are advanced.

It is appropriate here to note that the World Congress would not have been the success it turned out to be, nor even would it have taken place, without the cooperation of many individuals on several continents. Not least of these are Dr. Walter Juliff and his staff at Texas A&M University, whose hospitality made possible a meeting that was as enjoyable as it was productive. Also deserving of special mention is Dr. Ronald E. "Skip" Engel of the United States Food Safety and Inspection Service, who took the lead in organizing the 1993 World Congress. In addition to carrying out his responsibilities for many years as a senior USDA executive, he has served with distinction in a number of national and international organizations. Although unable to attend the Congress in person, Dr. Engel followed its activities closely. The papers issuing from the Congress describe the kind of sound food protection policy that has been a principal focus of his professional efforts.



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	James Marion
	Andrew McKenzie
	James Murray

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Recorder:	Tari Kindred
Participants:	James Egan
	Tom Feltmate
	Jack Haslam
	Peter Hewson
	G. A. Lam
	Hector Lazaneo
	Jack Leighty
	Anne MacKenzie
	Jeffrey Savell

IV. Residue Control

Speaker:	C. C. J. M. van der Meijs*
Discussion Leader:	Marvin Norcross
Recorder:	Jeffrey Brown
Participants:	Robert Biddle
	Ok-Kyung Kim
	Barry Marshall
	G. A. Mitchell
	Rhonda Nally
	Leon Russell
	Barnabas Sas
	Gary Smith
	Martin Terry
	Laurian Unnevehr

V. Postharvest Pathogen Reduction

Speaker:	Robert Biddle*
Discussion Leader:	John Prucha
Recorder:	Douglas Berndt
Participants:	Keith Baker
	Lee Christiansen
	Graham Clarke
	Richard Forsythe
	Jimmy Keeton
	Arthur Miller
	Rhonda Miller
	Rosemary Mucklow
	Reinhard Riemer
	Barry Shay

VI. Microbiological Criteria

Speaker:	Gary Acuff
Discussion Leader:	Ann Marie McNamara
Recorder:	Priscilla Levine
Participants:	Neil Armitage
	Ken Byrd
	William Dennis
	James Denton
	Brian Hogben
	Dae-Jin Kang
	John Nicholson
	Ian Sutherland
	Paul Vanderlinde

Observers:	James Hodges
	Wilson Horne
	Ken McDougall

* Participating in breakout group other than the topic addressed in the presentation.

1

TRADITIONAL POSTMORTEM INSPECTION

TRADITONAL POSTMORTEM INSPECTION

Breakout Group

Speaker: André Gravel
Discussion Leader: William James
Recorders: Robert Brewer
Charles Williams

Participants:

Ramon Cardinal
Walter Juliff
James Marion
Andrew McKenzie
James Murray

Introduction

Despite the improvement in many countries of livestock and poultry health, husbandry methods, food processing technology, and understanding of meatborne hazards, postmortem examinations of animals has been practiced for a long time with little change. The World Congress addressed the subject of traditional postmortem inspection. In a key paper, Dr. André Gravel described traditional postmortem inspection as a "relic of the past" that urgently needs reform, emphasizing public health to be relevant to the food safety needs of today.

Discussion

Traditional postmortem inspection was designed to ensure that meat and poultry are "safe and wholesome." Safety and wholesomeness concepts cover human health, but also imply the absence of aesthetic defects that the consumer deems objectionable. Traditional inspection has also been used to protect animal health through disease surveillance.

Most countries rely on postmortem inspection to ensure the safety and wholesomeness of products. Traditional postmortem inspection is an organoleptic system that uses the five senses to try to determine whether meat and poultry are "safe and wholesome." The elements of the system are listed in Dr. Gravel's paper. Actual procedures vary slightly from country to country and are tailored to animal health and socio-economic factors. However, in all these instances the inspection system still relies on traditional organoleptic postmortem inspection.

Strengths of Traditional Organoleptic Inspection. Traditional organoleptic inspection has been and still remains relatively successful in removing certain food safety hazards (e.g., pyogenic lesions) that are grossly visible or palpable, as well as numerous aesthetic defects (e.g., bruising), that occur in slaughter animals. Animal disease control programs also use inspection as a surveillance tool.

In many countries, traditional inspection continues to perform a valuable service in the fight against infectious disease and in maintaining sanitation standards in abattoirs. This activity has instilled confidence in the meat and poultry supply among consumers around the world. Traditional inspection has also facilitated access to international markets by providing a set of recognized standards.

Weaknesses of Traditional Organoleptic Inspection. While traditional organoleptic inspection provides a standard that is useful, it cannot be considered a "gold" standard. Reliance on traditonal organoleptic inspection has tended to lull consumers into a false sense of security because the system does not and cannot remove all meatborne hazards and prevent all human disease problems. Adherence to the concepts of traditional inspection has led to unrealistic expectations by the public.

The sensitivity of inspection procedures that make up organoleptic inspection varies greatly for the health hazards and aesthetic defects that the system was designed to eliminate from the food chain.

Because government inspectors are continuously present in abattoirs, the government *ipso facto* assumes some meausre of liability and a number of governments have been subject to litigation because of the presence of food poisoning organisms in raw meat and poultry products. Many of the aesthetic defects that the inspection

system was designed to remove and appear to be government's responsibilty are, in fact, quality issues and the responsibility for their removal should rest with industry.

Traditional organoleptic inspection focuses on end-product quality and safety. Microscopic contaminants from the skin and intestines, which are the cause of many health problems today, are not eliminated or even reduced. Traditional inspection methods, in fact, result in unnecessary cross-contamination. Required hands-on inspection techniques and incisions into such tissues as lymph nodes and bile ducts virtually ensure contamination is spread from one carcass to another.

Further, traditional inspection can limit production. The procedures required, whether or not they are effective, can result in reduced linespeeds. Where incision of organs or muscle tissues is incorporated in the body of procedures, traditional inspection can be destructive of product, or at least result in lower product quality.

Repetitive motion trauma, carpal tunnel disease, and other occupational safety problems may accompany traditional inspection.

The traditional inspection system has been unresponsive to change. Although the system is intended to support disease control activities, its potential utility in feeding back information to farmers on livestock quality has not been fully exploited. The system has been unresponsive to the dramatic improvement in animal health achieved in many countries. Continued adherence to procedures intended to detect diseases that have now reached a very low prevalence fails in any type of cost/benefit analysis.

Many zoonoses and organisms capable of causing foodborne diseases are carried by animals and exist in a subclinical state. Traditional postmortem inspection is of little use in addressing this serious risk category of meatborne hazards. These meatborne human pathogens are present before animals arrive at the slaughterhouse. Traditional inspection cannot detect them. This fatal weakness suggests, in fact demands, a shift in resource focus to other process controls within the slaughterhouse and to other components of the production, processing, distribution, and consumption cycle.

Changes Required to Address Current Risks. Decisive, rather than just incremental or technical, improvements must be made in the area of postmortem inspection. The microbiological health risks that the current system cannot detect or eliminate must be addressed. The responsibility for quality issues must lie where it rightly belongs. The kind of improvement needed can be effected in two phases. Phase one would involve transferring inspection tasks for aesthetic defects to personnel employed by the processor. There is also a need to ensure that inspection tasks performed have a scientific basis and have been subjected to risk analysis. Phase two would involve increasing resources in other areas so that the other components of production, processing, distribution, and consumption can be addressed. Application of Hazard Analysis and Critical Control Points (HACCP) in these areas is critical to reducing foodborne pathogens and resources must be applied by government and industry to achieve this goal.

Procedures can and must be modified on the basis of risk analysis. The responsibility for eliminating aesthetic defects that affect product quality can and should be transferred to industry. Scarce government inspection resources can then be more intensively focused on public health protection. An important result of the reallocation of resources can be strengthened linkages between slaughterhouse and on-farm surveillance, with strengthened pathogen control efforts. Pre-slaughter animal certification programs are a possibility. Consumer expectations of safe and wholesome product will continue to be met and, indeed, there will be improvement through pathogen reduction.

Barriers to Change. It can be expected that changes proposed in the traditional system of inspection will meet resistance. Possible sources of resistance are consumers,

industry, inspection personnel, food production workers, verterinarians, and importers and exporters. The prevailing cultures of government and industry can impede the implementation of systems based on HACCP or quality control (QC) principles.

The need to communicate and consult with groups likely to be affected by changes in the inspection system is clear from the recent experience of regulatory authorities attempting to implement system modifications. International consultation will be required to assure market access for distribution of products inspected under new standards and systems. Some consumers and certainly a number of interest groups will see any movement of inspection resources or transfer of responsiblity to industry as increasing public health risk. The fact that the opposite is true needs to be communicated to consumers and the blockage created by interest groups negated by rational scientific argument. This can be achieved by extensive consumer education programs and strict adherence to the principles of risk analysis.

Summary

Traditional postmortem inspection is a vestige of an earlier era. Though it once was based on current science and served an important animal and public health mission, serious flaws in the system have been exposed. While the animal diseases for which it was originally designed have been eradicated in many countries, the invisible threat of foodborne pathogens remains. Precious resources are squandered on procedures that are no longer needed. The system must be strengthened to ensure consumer confidence is maintained in the inspection process by concentrating resources where they will be used to the best effect.

Traditional inspection has been adopted by all trading countries and, because it has international sanction, it cannot be easily changed. However, there is a consensus in the international community that the system must be changed. It must be remodeled and reestablished on risk analysis principles and industry must accept its responsibilities. A HACCP or QC-like approach must be taken. Inspection resources must be shifted from end-product, or detection inspection, to process control monitoring and audit.

To establish the new system, regulatory authorities must be ready to evaluate risks that cannot be averted or controlled by the system. They must educate consumers, industry, and government employees in inspection principles, methods, and objectives. They must foster open communication among all stakeholders in the inspection system and arrange for consultation with affected groups in advance of major decisions on inspection.

2

PREHARVEST PATHOGEN REDUCTION

PREHARVEST PATHOGEN REDUCTION

Breakout Group

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Discussion Leader: Lonnie King
Recorder: Danny Lazenby

Participants:

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Introduction

Infectious foodborne diseases are of major importance worldwide. The World Health Organization (WHO) estimates that approximately 1.5 billion cases of foodborne illnesses occur annually. The potential for food to transmit infectious hazards is high in large part because of the many points along the food continuum at which safety can be compromised. Officials at the Center for Disease Control and Prevention (CDC) in the United States state that most pathogens enter the food chain at the farm, with broadening distribution occurring at slaughter. If this premise is correct, food safety does begin at the farm.

To buttress eroding public confidence in the safety of our food supply and to reduce the rising occurrence of human illness, there is a critical need to develop and implement an integrated "systems" approach to ensure a safer food supply. Food safety lends itself to an integrated systems approach from the farm to the table. The many points along the food chain must be fundamentally linked and considered as a single system. There are multiple jurisdictions, responsibilities, and activities shared by many people and groups along the chain that must be well coordinated. A breakdown at any single control point can produce new risks and hazards. Contamination of food can occur on the farm, during transportation, processing, distribution, storage, and preparation.

The first point along the food chain, the farm or production unit, is referred to as a "preharvest point," where producer decisions and production practices can influence all the remaining points of the chain. Preharvest food safety is an integration of husbandry with scientific and management principles. It is based on producers making scientifically valid and effective decisions in the prevention, elimination, or reduction of chemical and microbiological hazards. Preharvest may also include transportation issues that may be associated with microbial contamination or proliferation. A preharvest food safety program will require a responsible and accountable industry; proven on-farm interventions to reduce the risk of both chemical and microbial contamination; improved education and decisionmaking by producers that lead to safer practices; continuous research, learning, and improvement; improved diagnostic and monitoring capabilities; and a market-driven approach with built-in incentives and consumer acceptance.

Preharvest food safety stresses and is fundamentally based on disease prevention strategies rather than on reactions to unfortunate events. Adopting and extending quality management systems at the farm can serve as the framework for action. Implementing a Hazard Analysis and Critical Control Points (HACCP) scheme on the farm is viewed as the principal tool within this quality framework.

Discussion

As one considers designing and implementing a preharvest strategy, one quickly concludes that there are many more questions than answers about the topic and that data gaps are significant. There are several critical issues that must be addressed before a preharvest strategy can be transformed into a blueprint for action.

Animal Identification and Traceback Capabilities. An effective animal identification system is certainly the cornerstone of any preharvest food safety program. The best method for animal identification is based on four factors:

- Type of food-animal species
- National needs
- Traceback needs
- Methods of marketing

No "best" method, as such, clearly emerges for the identification of food animals and there is a need for flexibility, due to significant industry differences in the four factors. There are many differences internationally as well among potential models. The Australians' cattle identification system, using color-coded tail bands, is a unique example that serves their beef industry well, while other industries and countries prefer tattoos, backtags, and eartags. In some cases, the identification of herd-of-origin is appropriate, and in other cases identification of all individuals leaving a property is critical. Progression to unique identification for all animals is justified in some countries. There is a recognition and concurrence that new technological advances in the use of microprocessor chips will eventually lead to a superior identification method, especially when such technologies will also include measurements of animal health parameters, e.g., feed conversions, body temperature, weight, etc.

Part of the concept of preharvest food safety centers on the fact that consumers and producers perceive and understand a strong association between food-animal production and public health. Thus, it is axiomatic that accurate, efficient traceback to the farm is essential. There is a preference to be able to identify an animal back to birth; however, this is not always realistic, feasible, or essential. The multitude of system and marketing differences preclude a single recommendation. Successful intervention and control strategies associating pathogen reduction (cause) with improvements of animal and human health tracebacks are critical, so producers can correct inappropriate management practices and modify their behavior to achieve continuous improvement and improved quality.

Coordination of Data Management, Research Needs, and Risk Analysis. The greatest barrier to designing a preharvest food safety system is the lack of data and information. Many experts envision the use of risk analysis as part of the preharvest system. However, without baseline data on the prevalence of pathogens on the farm and their points of entry and better diagnostic tools, the essential data for risk analysis is missing. As data becomes available and ideally with better human health statistics, it will be possible to move from qualitative to quantitative risk analysis on the farm. The definition of risk also lacks clarity since the food chain has a series of end points to measure and consider. Data management systems do exist that could form the basis for much on-farm data analysis. The current animal health computer databases do not particularly lend themselves to preharvest programs but can be designed to better input and analyze pertinent preharvest data and help fill in some of the critical data gaps.

Because of the paucity of data, the main focus of a preharvest system must be on information-gathering through well-planned epidemiologic and research studies. We expect that there will be marked differences in the prevalence of pathogens under different management systems: for example, between intensively managed poultry and hogs and extensively farmed cattle and sheep. Data collected from one type of operation cannot be assumed to apply to other systems.

The use of epidemiologic methods is especially crucial. On-farm, case-control, prospective and risk-factor analysis studies are especially needed. Comprehensive field studies and research are also critical requirements and include:

- Incidence and prevalance of pathogens at the farm
- Ecology and natural history of farm microorganisms
- Rapid-testing and diagnostic methodologies
- Modeling and systems design
- Economic impact (effect)
- Designing surveillance and monitoring systems for diseases and pathogens
- Determining base-line levels for normal and at-risk animals

Also, funding difficulties and a lack of talented researchers who are knowledgeable and interested in these areas present significant challenges to conducting these important studies.

Roles of Participants and Driving Forces. A market-driven approach should be the foundation for a preharvest food safety program. The governmental role is seen as a combination of facilitation, oversight, and possibly auditing of quality assurance systems.

Although international differences are apparent, most industries respond to the economic incentives of adding value to their product and then receiving commensurate profits. A preharvest strategy does not necessarily require further regulations. A global marketplace and consumer demands help drive a competitive, market-driven system today. Consumer advocacy and societal concerns are clearly pushing production agriculture to respond to emerging needs.

Pathogen and hazard reduction on the farm may eventually lead to a product differentiation system based on herd or flock certification schemes. These schemes are based on implementing pathogen reduction processes at the farm and marketing products with this process guarantee. However, a minimum standard for food safety must not be compromised or suggested.

Quality management and assurance programs have been adopted by many food-animal industries worldwide. These programs are aimed at education and training of producers on day-to-day management practices that influence safety and wholesomeness of products. These systems carry through each stage of the food-animal production cycle. Besides achieving improved profits and better marketing positions, other incentives may also be available for producers who institute quality systems. For example, in Australia, a quality assurance program in beef cattle resulted in significant product improvement at slaughter, suggesting less costly and less stringent postmortem inspections can be the result, with reduced costs passed on the producer. The extension of accepted quality schemes to include preharvest food safety practices will only be feasible to the producer if the program is based on strong scientific evidence and is cost effective. Some quality management systems today already include environmental, animal well-being, conservation, and sustainability segments. Prevention represents a cost-effective alternative. The addition of preharvest processes can be viewed as part of this larger "ecosystem" framework where benefits accrue collectively.

Technology transfer and producer education are roles not only of industry but also of other nongovernmental health professionals. For example, in the United States, a large cadre of private veterinary practitioners is available to assist in these roles

as accredited veterinarians. In Denmark and Sweden, excellent feedback mechanisms between preharvest and postharvest inspections allow producers to better link and assess their on-farm performance to product improvement. Larger, vertically integrated production systems are also beginning to build in this feedback mechanism. In many countries, food and fiber networks consisting of retailers, distributors, advertisers, and ancillary businesses that depend on production agriculture for commodities are growing significantly. These groups thrive on adding value to products and developing new market niches, and they are putting pressure on producers to improve the quality and safety of their products; they are also exerting more control over which products are marketed and how they are differentiated.

An International Standards Organization (ISO) series of standards has recently emerged that had its genesis in engineering standards. ISO is an attempt to create product differentiation based on superior quality. It provides a third-party audit or validation component to ensure standardization and implementation of quality processes. A variety of products, some of which are food-related, are being marketed by organizations striving for higher quality through improved processes in areas like management, manufacturing, and distribution. There is a strong likelihood that food products and perhaps eventually animals themselves could be subject to standardized quality systems. Certainly, the verified production or quality assurance programs found in production agriculture today are similar in characteristics and philosophy to the ISO standards.

Cost and Benefits. Preharvest food safety programs have been implemented in Denmark, Sweden, Finland, the United Kingdom, and the United States involving *Salmonella* and *Campylobacter*. While these early efforts have been, in part, successful, enough information has been analyzed to conclude that properly designed and implemented preharvest programs will significantly reduce hazards and pathogens at the farm level. Yet careful attention must be given to the costs, benefits, and outcomes of such programs.

One attribute of preharvest safety programs is the change of emphasis from crisis management to prevention. In most cases, because the animal production chain is a pyramidal structure, it is more cost-effective to focus on reducing pathogens at the top of this structure; e.g., maintaining *Salmonella enteritidis* (Se)-free status in a few grandparent flocks helps ensure that thousands of laying hens are Se-free—a multiplier effect and benefit. Close scrutiny and study are paramount across the many events and points along the food chain. It may be feasible and more economically sound to reduce or eliminate certain pathogens at critical points other than preharvest sites. For example, communicating risks associated with improper food handling will certainly be required. Additionally, irradiation of certain end products could be a more cost-effective strategy than embarking on a preharvest effort.

Costs for a preharvest program will be financed, in large measure, by private industries, with some cost passed to consumers. However, European systems may tolerate greater government intervention and cost sharing. The benefits accrue from a reduction in human illness, greater consumer confidence, and creating new niche products and expanding markets. Some evidence also exists suggesting that combining pathogen reduction processes with quality management systems produces a synergistic benefit. As an example, poultry flocks in the United States engaged in Se preharvest activities enjoy fewer overall disease problems and improved rates of gain.

Goals. As preharvest programs are initiated, early success stories are especially critical. Early programs should focus on individual pathogen reduction programs such as reducing *E. coli* O157:H7. Thus, a "rifle shot" approach is encouraged rather than a wider, "shot gun" approach that includes multiple pathogen reduction strategies.

Certainly the critical points, as well as the intervention to reduce hazards, vary greatly depending on the microbe in question. In the United States, public health officials are targeting reductions in human disease outbreaks caused by *Salmonella, Campylobacter, Chlamydia , E. coli,* and *Listeria* by the year 2000. Thus, preharvest strategies might incorporate some of these microorganisms to assist in reaching targeted reductions in human illness.

Goals for preharvest programs must be designed for either pathogen reduction or total pathogen elimination. For most pathogens, reduction programs based on quality systems and continuous improvement is the only pragmatic approach. Yet, for a few pathogens the ultimate goal of elimination may eventually be feasible, e.g., trichina. Foodborne pathogens that are ubiquitous in nature obviously preclude elimination efforts at the farm level. Pathogen reduction strategies must be closely coordinated with similar strategies at other points along the food chain to be truly effective.

Summary

The reduction and prevention of foodborne diseases are complex problems without a solitary solution. An integrated systems approach involving all points along the farm to table food chain must be developed. Such a system involves expanding the narrow focus on traditional inspection of meat and poultry only at slaughter to a broader focus of multiple critical points along the food chain that also includes an on-farm pathogen reduction plan. The farm or production unit is the first point in the chain and decisions and practices on the farm have the potential to influence pathogen levels along the remaining points of the continuum.

The acceptance and success of a variety of quality management systems found in many food-animal industries may serve as an appropriate framework for future preharvest programs. Within a quality management system, on-farm pathogen reduction can be targeted using HACCP methods and also using the basic tenets of risk assessment. This system should be market-driven, principally voluntary, and involve an entrepreneurial partnership among government, industry, academia, and private animal health officials. An appreciation of the linkage of production agriculture with public health suggests the need for greater accountability across the food chain and especially on the farm.

The concepts of adding value to products and animals at the farm, continuous improvement through efficient traceback and monitoring loops, and the advent of national herd or flock health certification schemes will be integral to a successful preharvest program. Components of a preharvest plan include:

- Education
- Awareness
- Research
- Monitoring
- Producer feedback
- Process improvement

A successful program will possess the following characteristics:

- Cost-effective
- Pragmatic and flexible
- Broad-based support
- Industry buy-in
- Producer attitude and behavior changes

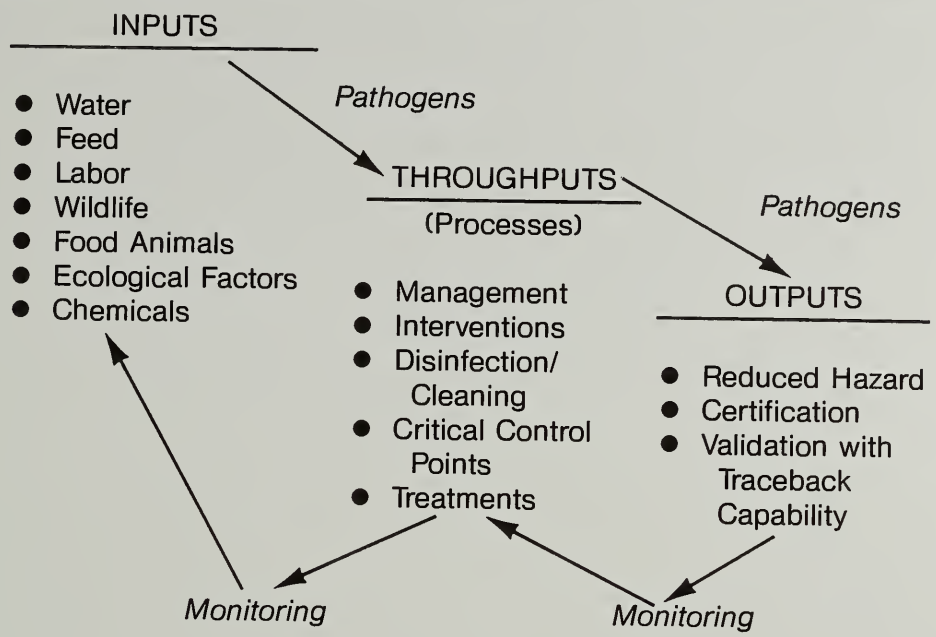
- Improved decisionmaking
- Improved animal and human health outcomes
- Viewed as a "win-win" strategy by all involved

There are past and present programs that might serve as potential preharvest models and give us encouragement based on their successes. Efforts to reduce *Salmonella* and *Campylobacter* in hogs and poultry have provided us with good insights and learning experiences. In the United States and other countries, setting and attaining standards for grade A milk is a worthwhile preharvest program to consider as a model. The successful reduction of trichinosis and the remarkable reduction of antibiotic residues such as sulfamethazine in U.S. hogs also serve as useful preharvest experiences and point out the contributions of private veterinary practitioners working closely with progressive producers.

Future program design requires an adequate preparation phase that stresses collecting data and information concerning on-farm pathogens, such as baseline measurements. Pilot programs focusing on single pathogen reduction goals and early successes before expansion efforts are undertaken are to be encouraged. Incentives, outcome assessment, and broad acceptance are also crucial to success. A model built on existing quality management systems that includes identification of critical points with appropriate intervention is logical. A practical model to consider (see diagram) incorporates three main phases: defining hazards and monitoring pathogens of farm inputs (water, feed, animal), adjusting throughputs or processes (management practices, treatments, intervention), and improving outputs (hazard reduction, certification with verification and monitoring).

Society demands safe food because it enhances human health and reduces health-related costs and the spread of potential pathogens. A preharvest food safety strategy is integral to successfully attaining these goals and meeting societal needs and expectations.

MODEL


INPUTS
Water
Feed
Labor
Wildlife
Food Animals
Ecological Factors
Chemicals
Pathogens
THROUGHPUTS
(Processes)
Management
Interventions
Disinfection/
Cleaning
Critical Control
Points
Treatments
Pathogens
OUTPUTS
Reduced Hazard
Certification
Validation with
Traceback
Capability
Monitoring
Monitoring

3
RISK ANALYSIS

RISK ANALYSIS

Breakout Group

Speaker: Steve Hathaway
Discussion Leader: Richard Carnevale
Recorder: Tari Kindred

Participants:

James Egan
Tom Feltmate
Jack Haslam
Peter Hewson
G. A. Lam
Hector Lazaneo
Jack Leighty
Anne MacKenzie
Jeffrey Savell

Introduction

Risk analysis is an important discipline that can significantly contribute to food safety for meat and poultry products. Risk Analysis comprises three components: Risk Assessment, Risk Management, and Risk Communication. The foundation of risk analysis is the process of risk assessment. Risk assessment is a systematic, scientific process of documenting potential hazards and characterizing the risk of adverse events associated with potential hazards either in a qualitative or quantitative manner. Risk assessment differs from the informal process of empirically estimating risks in that it must include the four components of risk assessment: hazard identification, hazard characterization, exposure characterization, and risk characterization. This formal process can be employed to assess a variety of complex risk situations for different hazards. Scientific value judgements and policy choices will be necessary at some decision points in the risk assessment process, and these judgements should be made using clear policy guidelines.

Risk analysis is valuable in regulatory programs to make the best use of available scientific data and information, to formalize the decisionmaking process, to assist in the allocation of resources, to facilitate agreement and understanding of regulatory decisions, and to communicate information about risk and management actions to the public and other interested parties. Risk analysis will be of increasing importance in facilitating the allocation of inspection resources proportional to public health and animal health hazards, establishing internationally accepted guidelines that are consistent and science-based, and improving the safety and wholesomeness of meat and meat products in local and international trade. Risk analysis will be useful in determining the public health and/or other risks when changes in production and inspection procedures are contemplated.

It is important to emphasize that risk analysis is not a process that will lead to the characterization of "zero risk" to consumers. Some degree of risk, no matter how small, will always be inherent in food products. Consumer responsibility is necessary for the proper handling and preparation of food products. This principle has been accepted internationally through the descriptions established by the Codex Committee on Meat Hygiene and adopted by the Codex Alimentarius Commission for characterizing the results of inspection as ensuring that products are "Safe and Wholesome."

Definitions

Several types of hazards and concerns relative to meat and poultry hygiene need to be addressed through risk analysis. These include human health hazards, animal health hazards, and aesthetic concerns. The World Congress Risk Analysis Working Group accepted the Quadrilateral Food Risk Analysis Committee (composed of government representatives from Australia, Canada, New Zealand, and the United States) draft definitions for Risk Analysis as appropriate for World Congress usage. A modification was made to the definition of a hazard by adding animal health hazards to the types of hazards to be addressed. The following definitions were written by the Quadrilateral Food Risk Analysis Committee.

Hazard—A biological, chemical, or physical agent or property that may cause a food to be unsafe for consumption, or aesthetically unacceptable to the consumer.*

Risk Analysis—A process consisting of three components: risk assessment, risk management, and risk communication.

*Additionally, hazards to animal health and food handlers are important and must be recognized and addressed.

Risk Assessment—A scientific process of identifying hazards, and estimating risk in qualitative or quantitative terms. This involves four analytical steps:

- *Hazard Identification*—The qualitative indication that a hazard(s) could be present in a particular food.
- *Hazard Characterization*—The quantitative and/or qualitative evaluation of the nature of the adverse effects—which may include a dose-response assessment.*
- *Exposure Characterization*—The quantitative and/or qualitative evaluation of the degree of human exposure likely to occur.
- *Risk Characterization*—Integration of the above steps into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainty.

Risk Assessment Policy—Predetermined guidelines for scientific judgements and policy choices which may be applied at specific decision points in the risk assessment process.

Risk Management—The process of weighing policy alternatives, selecting an appropriate regulatory option, and implementing that option.

Risk Communication—An interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and stakeholders.

Discussion

Food safety regulators must evaluate and manage different types of hazards and risks. Regulatory officials attempt to develop and implement appropriate regulatory actions to reduce the risk of hazards to as minimal a risk level as possible within an established risk-benefit-cost framework. Managers strive to approach the ultimate goals of "zero risk" while recognizing that "zero risk" may be unattainable in the real world. Resource limitations almost always impose restrictions on management options for risk reduction to "zero" levels.

Regulatory officials work to provide a high degree of assurance that inspected meat and poultry products are safe and wholesome. The World Congress Risk Analysis Working Group accepted the following description of "Safe and Wholesome" as elaborated by the Codex Committees on Meat Hygiene and used in all meat hygiene Codes of Practice.

"Safe and wholesome" refers to meat that has been passed as fit for human consumption using the criteria that it:

- Will not cause foodborne infection or intoxication when properly handled and prepared with respect to the intended use;
- Does not contain residues in excess of established Codex limits;
- Is free of obvious contamination;
- Is free of defects that are generally recognized as objectionable to consumers;
- Has been produced under adequate hygiene control; and
- Has not been treated with illegal substances as specified in relevant national legislation.

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* *Dose-response assessment*—The determination of the relationship between the magnitude of exposure and adverse effects.

Risk analysis can be used to address all hazards in meat and poultry products that contribute to "safety and wholesomeness."

The World Congress Risk Analysis Working Group recognized that an important component of effective food safety efforts is that a proportion of responsibility of food safety is shared by all of the individuals who have roles in the production, handling, processing, marketing, and preparation of food products. It should be noted that consumers share a particular responsibility in food safety by having a key role in the proper handling and preparation of foods.

Risk assessment can be utilized for a broad range of hazards and applications including biologic, chemical, and physical hazards. The application of this applied scientific field can produce valuable information for informed management decisions regarding the allocation of limited resources. Risk assessments are performed for specifically described scenarios. Risk assessments must utilize the four analytical steps of the risk assessment process; however, there can be substantial flexibility in the approach to using those steps. The assessment of risk should be separated from the selection of different risk management options.

Hazard Analysis and Critical Control Point (HACCP) programs employ elements of risk analysis and the decision to employ HACCP is a risk management option. HACCP employs a decision tree approach to identify unacceptable levels of hazards that are potentially controllable at different critical control points. It is clear that implementation of HACCP systems is strengthened through formal risk assessments to characterize potential risks from hazards. HACCP systems may then be tailored to control those risks assessed to be of greater significance.

Risk assessment and risk analysis have wide applicability to different processes and situations. The techniques and principles can be adapted for use in assessing the risk either quantitatively or qualitatively for virtually all regulatory activities. The use of risk analysis for chemical hazards in one form or another is a well established discipline and the application of risk assessment techniques for biologic risks is beginning to develop. Risk analysis is becoming a valuable discipline in establishing scientifically justified postmortem inspection systems.

Biologic risk assessment in food hygiene presents a particular challenge due to the complexity of host-pathogen interactions and the scenarios for food processing, storage, distribution, handling, and preparation that must be addressed. The need for appropriate biologic data is a major limiting factor in performing biologic risk assessment, especially in terms of infectious dose-response curves and true human exposure data.

In the future, different countries may use different concurrent methods of evaluating risks for different applications. For example, it may be common to employ the empirical estimation of risks for some applications, formal qualitative risk assessment for others, and formal quantitative risk assessment for other applications at any given time. The lack of appropriate biologic data is often the major limiting factor in forcing the use of qualitative rather than quantitative risk assessment.

The advantage of formal risk assessment is that it provides an established framework for the assessment of risks. Thus, it facilitates the acceptance of the completed risk assessments by the interested parties. Risk assessments present information in a clear manner so that all stakeholders can readily understand the underlying reasons for certain management decisions.

It is useful to have the ability to prioritize the hazards that may potentially be assessed through risk assessment procedures. A qualitative ranking system can be used to perform preliminary assessments of the hazards that may be addressed through risk assessment. For example, potential hazards can be ranked by severity of adverse

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RESIDUE CONTROL

RESIDUE CONTROL

Breakout Group

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Introduction

The control of residues from animal drugs, pesticides and herbicides, and environmental contaminants is an important factor in food safety. Residue control also plays a key role in the international trade of animal-derived food and products. For these reasons, most developed nations maintain systems of residue control both for internal production and import/export purposes. By and large, these systems are similar in design, scope, and application. Generally, regulatory action is taken as a result of end-product testing that returns a violative result for a particular sample. Standards for acceptable levels may be determined by recommendations of international bodies, governmental approval, and registration processes for drugs and pesticides, or by administrative directive for environmental contaminants.

Laboratory and in-plant tests are conducted on samples for residues of concern. Sampling may be directed at specific animals or classes of animals on the basis of information or indications that violative residues may be present. For many years, however, most residue control systems have emphasized random, statistically determined, nationwide monitoring of a wide range of compounds and food animals and products. Monitoring programs of this nature emerged largely in response to widespread public demand in the 1960s for a clearer picture of the extent of residues, primarily from pesticides, in food.

Today, near the end of the century, the problems addressed by comprehensive monitoring have largely dissipated. With few exceptions, chemical hazards in food are either nonexistent or occur in such small concentrations that adverse health affects are unlikely to result in the exposed population. Maximum Residue Limits (MRLs) include large safety factors, and violations are generally a matter of noncompliance with a regulatory level rather than a significant public health concern.

The current pattern is one of very specific problem areas, such as certain compounds, discrete classes of animals, or particular conditions for misuse. A highly important factor in the current world economy is the significant expense of comprehensive monitoring, particularly when it is related to the limited pertinent benefits that accrue.

Discussion

There is a need to identify new directions for residue control to take in preparation for the next century. Potential public health risks and regulatory concerns would be met more efficiently by a more selective and discriminating residue control system, one based upon sound scientific principles. Risk-based residue control systems, aimed at specific problem areas, would direct resources to where there are genuine needs and thus provide cost-effective results.

It should be noted, however, that there are both a public health concern as determined by science, and a public anxiety regarding chemical residues, which may not be scientifically based. There is a widespread consumer perception that no residue, legal or otherwise, is acceptable. Thus, factors that are nonscientific, but nevertheless compelling to many, may influence residue policy for some time to come. Very broad-based monitoring, however out-of-date, may persist in one form or another in response to public demand for assurance regarding the emotional issue of residues in the foods they eat. Monitoring may also be appropriate for a period after the introduction of a new drug or agricultural chemical, so as to determine the pattern of residue, if any, associated with its use.

Risk-based, scientific residue control systems should be based on evaluations of compounds in terms of their use, relative toxicity, and capacity to expose animals or humans to their residues, as well as food consumption factors. The compounds to be targeted and the varying emphasis given to them should be determined by local residue concerns, trade factors, and international scientific guidance. Such guidance is provided by organizations such as the Codex Alimentarius Commission, the International Technical Consultation for Veterinary Drug Registration, and the Office International des Epizooties. In fact, guidelines for a residue control system have been described by the Codex Alimentarius Commission (1) and are in final preparation for dissemination.

An international framework for residue control would make possible the harmonization of residue system standards and allowable residue concentrations, the Maximum Residue Limits (MRLs), between countries who trade in food products. Residue control of imports should follow the same principle that is applied to domestic product of the importing country, i.e., reliance on scientifically based risk assessments and sampling procedures. Countries should recognize the equivalence of scientifically based registration/licensing systems, as appropriate. As such, a chemical licensed in one country should not be an impediment to trade simply because it is not approved in the importing country. Harmonization, based on these standards or acceptable future modifications, would greatly facilitate free trade and thereby strengthen the key agricultural sections of national economies.

Within the individual nations, the historical emphasis on detection and enforcement should be gradually replaced by an integrated approach to residue control comprising government, producers and producer associations, the pharmaceutical and agrichemical industries, veterinary practitioners, and consumers. The Hazard Analysis and Critical Control Point (HACCP) approach is becoming an internationally recognized means of addressing food safety concerns. HACCP could provide the practical instruments needed. The goal of this approach would be an effective quality assurance system where all parties involved participate in the common endeavor of preventing violative residues through proper use and avoidance of environmental contaminants. Other elements of an acceptable control system could include buyer-seller contracts, with provisions for liability, and comprehensive ''traceback'' systems of animal identification.

Government authorities should actively encourage the education of producers in proper drug and pesticide use and avoidance of environmental contaminants, and should perform quality-assurance testing of both domestic and imported product. Such testing activities, together with regular review of domestic producer and exporter QA programs, would promote compliance. Economic incentives could also stimulate the development of rapid test methods that could be employed on the farm as part of a producer's quality-control process.

A key function for government, as well as industry, should be to inform the public regarding potential risks in food, and thereby seek to alleviate unfounded concerns. Consumer education is a crucial aspect of any modern residue control system. Government bears the general responsibility of properly regulating industry quality control efforts so as to provide credible assurance to the public and to trading partners that the appropriate procedures to protect public health are being followed.

Summary

The control of residues from animal drugs, pesticides and herbicides, and environmental contaminants is an important factor in food safety and international trade of animal-derived food and products. Current systems of residue control evolved in the 1960s and are based on random, statistically determined, nationwide monitoring of a wide range of compounds and products. Today chemical hazards in food are less prevalent and significant. There is a need for a residue control system based upon sound scientific principles and aimed at those residues that present potential public health risks or regulatory concerns. Risk-based residue control systems would

direct resources to where there are genuine needs and thus provide cost-effective results. Residue control of imports should follow the same principle that is applied to domestic product of the importing country: reliance on scientifically based risk assessments and sampling procedures. Countries should recognize the equivalence of scientifically based registration/licensing systems as appropriate. Harmonization, based on these standards or acceptable future modifications, would greatly facilitiate free trade and thereby strengthen the key agricultural sections of national economies. Government authorities should actively encourage the education of producers in proper drug and pesticide use and avoidance of environmental contaminants, and should perform quality-assurance testing of both domestic and imported product. Economic incentives could also stimulate the development of rapid test methods that could be employed on the farm or in-plant as part of a producer's quality-control process. A key function for government, as well as industry, should be to inform the public regarding potential risks in food, and thereby alleviate unfounded concerns. Government bears the general responsibility of properly regulating industry quality-control efforts so as to provide credible assurance to the public and to trading partners that the appropriate procedures to protect public health are being followed.

Reference

(1) Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods. Report of the Sixth and Seventh Sessions of the Codex Committee on Residues of Veterinary Drugs in Foods, Appendix VIII.

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POSTHARVEST PATHOGEN REDUCTION

POSTHARVEST PATHOGEN REDUCTION

Breakout Group

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Introduction

As noted in the introduction to the report on Preharvest Pathogen Reduction, millions of cases of foodborne disease occur annually world-wide. A large percentage of these cases is associated with foods of animal origin.

The postharvest point of the food chain begins at the slaughter house and includes further processing operations, product distribution and storage, and, ultimately, handling and preparation by the consumer.

Today, food animals often arrive at the slaughter house carrying human enteropathogenic microorganisms on their external surfaces or in their alimentary canals. These animals are usually healthy and show no signs of disease. The slaughterhouse is not a sterile surgical operating room; thus there is a risk that raw meat and poultry may contain pathogenic miccroorganisms.

Nevertheless, there are a number of measures that can be taken by the food processor, inspection services, and the consumer to reduce and control pathogens associated with meat and poultry and thereby prevent meatborne disease.

Discussion

Meatborne Pathogens. The pathogens of principal concern today associated with raw or undercooked meat and poultry are: *Salmonella* spp., *Campylobacter jejuni,* and enteropathogenic *Escherichia coli* (O157:H7). Pathogens associated with cooked ready-to-eat meat that are of major concern today are those identified above and additionally *Listeria monocytogenes, Staphylococcus aureus,* and *Clostridium perfringens.*

Other pathogenic microorganisms, including viruses and protozoan parasites, are recognized as causing foodborne illnesses. However, their relationship to the current incidence of foodborne disease remains to be elucidated.

Educational initiatives and reduction/control techniques that are focused on the organisms of principal concern today (identified above) associated with meat and poultry will also reduce and control other pathogenic microorganisms that are associated with meatborne diseases.

Risk of Meatborne Disease. There is a risk of illness from pathogens of current concern associated with raw meat and poultry. The risk of illness is essentially zero if meat and poultry are handled properly. The risk of illness will increase substantially when:

- Meat and poultry are eaten raw.
- Meat and poultry are improperly cooked.
- Uncontaminated meat and poultry become contaminated with pathogens from other sources, such as raw food, the environment, food handlers, etc.
- Meat and poultry are time and/or temperature abused, that is, they are handled improperly, thereby allowing bacteria to multiply to levels that may cause illness.

Communicating Risk. The communication of risk to the public is a complex issue that has not been totally successful. Long- and short-term strategies must be developed to focus on specific groups that may have unrealistic expectations regarding the safety of raw meat and poultry.

Both the industry and inspection agencies have responsibility for communicating risk. The information must be communicated in language that is simple and clear.

There are numerous ways to communicate the risk to the public. Examples that have proven to be effective include short television news spots by TV celebrities, instructional labeling stickers, food safety pamphlets, food safety videos, and many others.

Public communication is very expensive. The industry and inspection agencies must allocate the appropriate resources if the public is to be adequately informed about food safety. Communication of risks associated with meat and poultry products will probably never be 100% successful. Efforts may only be considered successful when the incidence of meatborne disease significantly decreases.

The Responsibility of Industry. Food processors have an economic and moral responsibility to provide their customers with safe and wholesome product. The industry can be expected to aggressively work towards reducing the level of pathogens on fresh meat and poultry, including the investment of significant resources and capital, when there is a clear economic payback.

Further, the industry can be expected to take appropriate action when scientific studies and data show that specific production practices will have a measurable effect on the level of pathogens on meat and poultry products.

When a food processor's product is associated with an illness, the likely outcome is litigation. Experience from a number of food-related disease incidents has demonstrated the value of having a legally defensible position. In the United Kingdom, changes to food safety legislation, specifically the inclusion of the "Due Diligence" clause in the 1990 Food Safety Act, have appeared to change the way processors view food safety. "Due Diligence" enables food processors to mount a defense against litigation if the processor can prove everything reasonable was done to ensure best practices were undertaken. This defense has already been used successfully a number of times by food suppliers or manufacturers when cases were brought against them. Regulators in the United Kingdom believe the "Due Diligence" provision has had a positive impact on the reduction of foodborne illnesses.

End-Product Handling and Cooking. Approximately 97% of foodborne illnesses can be traced to mishandling or inadequate preparation of food prior to consumption. This fact indicates that targeting the control of pathogens principally at the end-product handling and cooking point of the "farm-to-fork" food chain will not be sufficient by itself to prevent meatborne illness.

The higher the microbiological quality of the product, the greater the margin of safety against possible end-product mishandling or undercooking. Therefore, to keep the risk of foodborne illness at the lowest possible level, a sufficient margin of safety must be designed and incorporated into all stages of the food process, not just end-product handling and cooking.

Pathogen Load on Meat and Poultry. It is not possible with present manufacturing practices and technology to completely prevent pathogens on raw meat and poultry. The pathogen load on raw meat and poultry is often directly related to the pathogen load brought in to the slaughterhouse by the live animals.

There are techniques that are known to be effective for controlling cross-contamination of product and they should be routinely utilized.

The industry's capability for producing the best possible product using good manufacturing practices has not been determined. Whatever the pathogen level is determined to be when GMPs are used, the level should be considered a dynamic target and continuous improvement should be sought.

Thus it is imperative that plants document improvements and make any improvements to food safety technology widely known. In so doing, the entire industry will progress and consumer protection will be maximized.

Decontamination of Meat. A number of "decontamination" technologies are available, including the use of organic acids, trisodium phosphate, hot water flumes, and hyperchlorinated rinse water. Experience indicates these technologies vary in their ability to reduce spoilage organisms and pathogens, depending on a number of known and unknown factors. They cannot be expected to sterilize raw meat and poultry. It should be noted at the present time that the European Union does not permit the "decontamination" of food animal carcasses by washes containing either water or a variety of sanitizing agents.

Irradiation is also an effective technology for reducing or eliminating a number of spoilage and pathogenic microorganisms. However, at the levels of irradiation presently approved, bacterial spores such as *Clostridium perfringens* are not destroyed.

"Decontamination" measures are an adjunct to and not a substitute for Good Manufacturing Practices. In order to reduce and control the pathogen load on raw meat and poultry, food processors must focus on all points of the production process. Good Manufacturing Practices should aim to "minimize contamination and maximize decontamination."

Hazard Analysis and Critical Control Points (HACCP). Experience by both industry and inspection agencies has shown that "detection inspection" involves extensive examination of product and is extremely difficult to achieve on moving production lines. Organoleptic inspection techniques are considered insensitive tools for the control of invisible microbiological hazards. Therefore, process control and prevention techniques are needed to address the microbial risk and to provide adequate levels of food safety.

Over the last several years, many scientific committees and groups have strongly recommended HACCP as the process control system to best address food safety. HACCP systems should be considered an essential part of a food production system. HACCP systems interface well with other quality assurance procedures, such as total quality management, statistical quality control, etc.

HACCP systems, by themselves, will not guarantee pathogen reduction/control. They must be plant-specific and be designed specifically to control, minimize, and prevent product contamination. And they must be routinely applied as they were designed.

HACCP and ISO 9000. The principal purpose of the HACCP and ISO 9000 systems is ensuring product safety and quality. Both systems are considered compatible for food regulation control purposes.

A complete ISO 9000 system is designed to go beyond regulatory and food safety concerns; additionally, these systems ensure that product conforms to a standard that will meet the customer's required quality specifications.

ISO 9000 systems provide the framework for a management system into which specialized components, such as HACCP, may be integrated.

HACCP Implementation. HACCP can be implemented by government decree (mandated) or on a voluntary basis. The industry can be expected to embrace HACCP proportionate to the benefits and costs associated with managing its production processes in a HACCP way.

In a number of countries, inspection service is provided on a cost-recovery basis. A HACCP program designed to meet all regulatory requirements should normally require little regulatory resources for verification as compared to traditional "detection inspection." In such situations, a clear economic incentive would exist to operate in a HACCP way; thus most plants would logically be expected to do so if given the option. In such cost-recovery systems, most recalcitrants and stragglers would probably accept mandatory HACCP knowing that it makes economic sense.

In an inspection system where there is no financial incentive to operate in a HACCP way, costs to the regulatory authority to enforce compliance can be expected to be substantial, in some cases prohibitive.

A high proportion of processing operations are currently operating in a HACCP way, albeit "informally." That is, there is no HACCP program available to the regulatory authority and there is little or no documentation. However, there probably would be general acceptance by this group of operators of mandatory HACCP because compliance would not be overly burdensome.

Most slaughter operations, on the other hand, do not currently operate in a HACCP way and voluntary HACCP would probably not be significantly adopted. Mandatory HACCP, unless accompanied with an economic incentive, would be difficult and costly to effectively implement.

There are other factors that would, to some extent, encourage plants to operate in a HACCP way. For example, a formalized HACCP program is a good defense against possible litigation. Also, HACCP fits well into a self-directed workforce type of management.

Pathogen Reduction vs. Linespeeds. Poor process control can result in an increase in pathogens on meat or poultry carcasses. Experience has shown that high speed slaughter plants can have either good process control or poor process control. Likewise, slow speed plants can have good process control or poor process control. Poor process control includes such things as poor performance and supervision of plant production line workers, lack of equipment sanitation, congestion of product, etc.

A recently published study comparing beef slaughter plants reported that plants with the highest volume (linespeeds) produced the cleanest product microbiologically. This may be because the higher linespeed plants were under better process control than the slower speed plants.

Process control is the key, not linespeeds per se.

HACCP-Based Inspection. In order for inspection to be HACCP-based, a food processor must be operating in a HACCP way. If there is no formalized HACCP program, or inadequate plant monitoring, or insufficient documentation, then verification by the inspection agencies is not possible.

However, even if a HACCP system cannot be implemented at a meat plant, there would be advantages to having both plant personnel and regulatory staff trained in HACCP principles that they can use in a disciplined approach to food safety.

A traditional detection inspection system and a "HACCP-based" verification inspection system may coexist in a plant for a period of time. This type of evolutionary implementation plan would allow the plant to collect and document production data to support the plant's commitment to HACCP. At the same time, inspection personnel would be demonstrating a change in their inspection activities from one of "detection inspection" to verification of the plant's process control mechanisms.

Summary

The occurrence of pathogens on raw meat and poultry is directly related to the occurrence of pathogens on the live food animals. The principal pathogens of concern today for raw and undercooked meat and poultry are *Salmonella* spp., *Campylobacter jejuni,* and enteropathogenic *Escherichia coli* (O157:H7). For cooked, ready-to-eat meat and poultry, the three above pathogens plus *Listeria monocytogenes, Staphylococcus aureus,* and *Clostridium perfringens* are of principal concern. These pathogens can cause foodborne illness if meat and poultry is improperly handled or inadequately cooked. Food processors and consumers can avoid foodborne illness if they know and respect the risks associated with meat and poultry. Risk communication is the responsibility of both the industry and inspection agencies. Public communication is expensive and the necessary resources must be allocated to ensure effective communication of food safety.

Focusing all pathogen control efforts solely on end-product handling and cooking will never be 100% successful, so it is essential that food processors continuously strive to produce raw meat and poultry that contain low levels of pathogens.

Food processors have the responsibility for producing a safe product. HACCP is the best approach for the industry to reduce and control microbiological hazards associated with raw meat and poultry. A number of emerging technologies such as organic acid washes, hot water washes, irradiation, et al., can be valuable in the control of pathogens. They can be an adjunct to a HACCP program, but not a substitute for Good Manufacturing Practices designed to minimize contamination in the first place. HACCP is also the best approach for controlling and preventing pathogen contamination of processed meat and poultry, including cooked, ready-to-eat product.

In order for meat and poultry inspection to be HACCP-based, a food processor must operate using HACCP principles. The meat and poultry industry can be expected to embrace HACCP proportionate to the benefits and costs associated with managing its production processes in a HACCP way. A regulatory authority might require plants to utilize a formal HACCP program. When the benefits are clear or the regulatory burden is minimal, a high degree of compliance can be expected. However, in the absence of appropriate incentives, mandatory HACCP can be expected to be difficult and costly.

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MICROBIOLOGICAL CRITERIA

MICROBIOLOGICAL CRITERIA

Breakout Group

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Introduction

Our food supply consists primarily of animals, plants, and products derived from them. These animals and plants are produced in association with soil, water, and air; therefore, exterior surfaces will likely be contaminated with a variety of microorganisms from these sources. Some of the microorganisms contaminating the product may be used to produce desirable changes in the food. Other microorganisms present on the product may cause quality deterioration or spoilage of the food, and some may cause foodborne disease. Successful commercial production of a food product requires control of microbiological presence and activity to achieve maximum shelf life consistent with safety of the product. Microbiological criteria can provide a tool for evaluating the acceptability of a food or process designed to control the presence or growth of microorganisms. However, development and application of microbiological criteria must follow established basic principles and success will depend upon a thorough understanding of the food production process and the significance of various microorganisms present.

Definitions

A microbiological criterion is a quantity upon which a judgement or decision regarding acceptability of a food or food product can be made. In most cases a criterion will specify that a certain microorganism, a group of microorganisms, or toxin produced by microorganisms be absent or limited in presence in a specified quantity of food or ingredient. A microbiological criterion should include the following information (NRC, 1985):

- A statement describing the identity of the food or food ingredient,
- A statement identifying the contaminant of concern,
- The analytical method to be used for the detection, enumeration, or quantification of the contaminant of concern,
- The sampling plan, and
- The microbiological limits considered appropriate to the food and commensurate with the sampling plan.

Criteria may be mandatory or advisory. A mandatory criterion may not be exceeded and food that does not meet the specified limit is required to be subjected to some action, including rejection, destruction, reprocessing, or diversion. An advisory criterion permits acceptability judgements to be made, and should serve as an alert to deficiencies in processing, distribution, storage, or marketing.

Widely used types of criteria in the international food industry include standard, guideline, and specification. The following definitions were recommended in 1985 by the National Research Council's Subcommittee on Microbiological Criteria for Foods and Food Ingredients (NRC, 1985):

- **Standard**—a microbiological criterion that is part of a law, ordinance, or administrative regulation. A standard is a mandatory criterion. Failure to comply constitutes a violation of the law, ordinance, or regulation and will be subject to the enforcement policy of the regulatory agency having jurisdiction. Microbiological standards may be useful when epidemiological evidence indicates

that a food is frequently a vehicle of disease. To be effective, the standard must attain its stated objective, namely the elimination or reduction of foodborne disease.

- **Guideline**—a microbiological criterion often used by the food industry or a regulatory agency to monitor a manufacturing process. Guidelines function as alert mechanisms to signal whether microbiological conditions prevailing at critical control points or in the finished product are within the normal range. Hence, they are used to assess processing efficiency at critical control points and conformity with Good Manufacturing Practices. A microbiological guideline is advisory; however, management or regulatory agencies may require the conditions responsible for persistent microbiological deficiencies to be immediately corrected. Industry guidelines are often of a proprietary nature and may vary for the same product produced by different companies.

- **Specification**—a microbiological criterion that is used as a purchase requirement whereby conformance becomes a condition of purchase between buyer and vendor of a food or ingredient. A microbiological specification may be advisory or mandatory.

Discussion

Value of Setting Microbiological Criteria. With careful design and implementation, uniform microbiological criteria can ultimately enhance food safety and elevate consumer confidence in the commercially processed food supply. Microbiological criteria developed cooperatively by industry and government can equip the food industry and regulatory agencies with guidelines for enhanced control of food processing systems. However, establishment of any criteria must be based on a thorough knowledge of food processing and must be product-specific.

The ultimate purpose of utilizing these criteria is to protect the public health by potentially reducing the presence of foodborne pathogens.

Microbiological criteria may also be used to make decisions regarding the acceptability of products if designed to measure adherence to Good Manufacturing Practices. They can also be used to determine the appropriateness of a food or ingredient for a specific purpose. In addition, industry quality assurance programs may use criteria to monitor the potential shelf life of perishable foods.

Establishment and Implementation of Criteria. It is not practical nor necessary to establish microbiological criteria for all foods. A microbiological criterion for a food or food ingredient should be established and implemented only when there is a recognized need and when the criterion can be shown to be effective and practical. The criterion must accomplish its objective. Additional factors to be considered include (NRC, 1985):

- Evidence of a hazard to health based upon epidemiologic data or a hazard analysis,

- The nature of the natural and commonly acquired microflora of the food and the ability of the food to support microbial growth,

- The effect of processing on the microflora of the food,

- The potential for microbial contamination and/or growth during processing, handling, storage, and distribution,

- The category of consumers at risk,

- The state in which the food is distributed,

- Potential for abuse at the consumer level,
- Spoilage potential, utility, and Good Manufacturing Practices,
- The manner in which the food is prepared for ultimate consumption,
- Reliability of the methods available to detect and/or quantify the microogranism or toxin of concern, and
- The cost/benefit associated with the application of the criterion.

Appropriate Criteria. Recognizing that quality and safety issues may overlap in practice, these concepts are discussed separately to emphasize how appropriate criteria may be applied.

Quality. The relationship between good commercial practices and quality of a food is often a question of aesthetics. In addition, microbiological quality criteria are often based upon the assumption that quality will vary inversely with numbers of microorganisms. That assumption may only be true for specific foods under a specific set of conditions. However, with sufficient background data, the following attributes of food may be measured to some extent (NRC, 1985):

- Shelf life as perceived by specific attributes,
- Adherence to Good Manufacturing Practices, and
- Utility of a food or food ingredient.

Safety. Microbiological criteria designed to provide an indication of a safety of a food or food ingredient should be developed only when a microbial hazard can be reduced or eliminated by the application of criteria. Development of criteria cannot be set until the risk of the microbial hazard has been defined through a risk assessment process. In the absence of quantitative risk assessment, tolerance limits for pathogens cannot be ascertained, making qualitative risk assessment the basis for setting criteria. Because of this, current criteria for food safety can provide guidelines that promote better food quality. Safety criteria are often based upon tests for indicator microorganisms whose presence suggest the *possible* presence of a hazard, not the presence of the hazard itself. Tests for indicator organisms may be used when a relationship between the occurrence of the indicator organism and the likely presence of a pathogen or toxin has be established. Direct tests for pathogens or their toxins are less routinely applied.

Some raw foods are commonly contaminated with potentially dangerous microorganisms, and the presence of these organisms may be considered an inherent defect in the product. In this situation, application of microbiological safety criteria is inappropriate. It would be unrealistic to exclude certain raw products from the food supply simply because they contain potentially dangerous microorganisms when they could be rendered safe for consumption through proper processing and cooking. For these reasons, Hazard Analysis and Critical Control Points (HACCP) programs should be applied to the production of raw products in order to monitor processing trends and to identify and correct processing deviations. In raw processing, microbiological quality criteria may be appropriate to verify critical control points. Further complicating the issue of applying microbiological criteria to raw products is the the extreme variability of pathogens like *Salmonella* in raw meats, which prevents the establishment of practical sampling plans, which would ensure the absence of the pathogen with any degree of confidence. Microbiological safety criteria have less importance regarding food that must be cooked than for products that are ready to consume. For fully processed, ready-to-eat products, setting microbiological safety criteria may be more appropriate since the product is subjected to microbiological kill steps, such as cooking or the addition of anti-bacterial components (i.e., bacteriocins). In these instances, microbiological criteria may be applied in a HACCP

program at the critical control step of cooking. However, criteria should not assigned arbitrarily, but only on sound scientific principles. CCP criteria should be set by producers, based on a thorough knowledge of the specific process, with application at specific defined production points and with a stated, defined detection methodology.

Sampling. One of the most essential components of a microbiological criterion is an effective sampling plan. To examine a food for the presence of microorganisms, either the entire lot must be examined or a representative sample should be obtained. A lot is defined as the quantity of product produced, handled, and stored within a limited time period under uniform conditions. Since it is impractical to examine the entire lot, statistical concepts of population probability and sampling must be used to determine the size of the sample from the lot and to provide conclusions drawn from the analytical results. The lot is made up of sample units, and a sufficient number of units must be selected from the lot for microbiological evaluation to determine the acceptability of a lot. The sampling plan must be designed so that it rejects inferior lots within a set level of confidence. Detailed information regarding statistical concepts of population probabilities and sampling, choice of sampling procedures, decision criteria, and practical aspects of application as applied to microorganisms in food can be found in a publication by the International Commission on Microbiological Specifications for Foods (ICMSF, 1986).

Two-class plans. A simple method for determining whether to accept or reject a food lot can be based upon a microbiological test conducted upon several randomly selected sample units (*n*) with a preset maximum number of sample units allowed to yield unsatisfactory results (*c*). The test will usually determine the presence or absence of an organism or it will determine whether samples are above or below a preset concentration (*m*). Thus, in a two-class sampling plan designed to make a presence/absence decision on the lot, n=5, c=2 means that 5 sample units are obtained and examined; if more than 2 of the samples show the presence of the organism of concern, the lot is rejected.

Three-class plans. Three-class plans were designed for situations in which the quality of the product can be divided into three attribute classes based upon the concentration of the organisms within the sample units; O to *m*, *m* to *M*, and greater than *M*. The level of the test organism that is acceptable in the food is denoted by *m*. *M* is a hazardous or unacceptable level of contamination. Any count above a concentration *M* is considered unacceptable; therefore, a count from any of the *n* sample units exceeding *M* will result in rejection of the lot. In a three-class plan, *c* indicates the number of sample units that can contain a concentration above *m* but only up to and including *M*. This classification of sample units has been determined to be less than desirable, but a few of sample units (*c*) will be allowed without rejecting the lot. Thus, in a three-class sampling plan, the food lot will be rejected if any one of the sample units exceeds *M* or if the number of sample units with contamination levels from *m* to *M* exceeds *c*.

The sampling plan specified in a microbiological criterion should be appropriate to the hazard expected to be associated with the food. This expected hazard should be determined by the type of organism expected to be encountered as well as by expected handling conditions to be applied after sampling. A more stringent sampling plan should be used as the expected degree of hazard increases. Stringency is affected by the number of sample units obtained from a particular lot (*n*) and by the number of samples (*c*) allowed to be marginally acceptable or defective. ICMSF (1986) proposed a system for classification of foods according to risk into 15 hazard categories called cases, with suggested appropriate sampling plans (Table 1).

Microbiological Components and Analytical Methods. Microorganisms as components of microbiological criteria for foods include pathogenic bacteria and their toxins and indicator organisms. Adequate and practical methods must be available to detect or enumerate the microbiological component if the criteria are to be effective. Appropriate pathogenic bacteria useful as components of microbiological criteria include those that are likely to be found in the food, which then becomes a vehicle

for transmission of the organism to the consumer. Suitable indicator organisms are those whose presence indicates:

- The likelihood that pathogens or toxins may be present,
- The likelihood that faulty practices occurred that may adversely affect safety or quality of the product, or
- That the food or ingredient is not suitable for the intended use.

The real significance of indicator organisms as food contaminants can be understood only by having a thorough knowledge of the microflora of the production environment and the process.

Disposition of Product. *The action to be taken when a microbiological criterion is exceeded depends upon the purpose for establishing the criterion.* Criteria may be established for purposes ranging from acceptability of raw materials to monitoring of critical control points to acceptability of the finished product. Willingness to accept the defined appropriate action will depend heavily upon the intelligent establishment of rational and defensible criteria. Foods determined to be a direct health hazard will require cautious consideration when alternatives other than total destruction are surveyed. However, destruction of a finished product is costly, and alternative actions should be sought and used whenever possible. Reliance placed upon monitoring of critical control points to give assurance that a process has been properly applied will reduce the probability that destruction of a product will be required based upon finished product testing. Evidence that a critical control point is not under control should generate immediate action, preventing future occurrences, and may provide immediate correction of the situation before destruction or rerouting of the product is required.

Cost of Criteria Implementation. Implementation of reasonable and effective microbiological criteria can provide for enhanced food safety and efficient trade. The cost of implementation of microbiological criteria is offset by the possible reduction in foodborne disease, the reduction in finished product destruction, and the more efficient movement of products through trade channels. Cost-benefit studies are required to determine an accurate cost of implemenation and will depend on the accuracy of costs of the illness to be reduced as well as the costs of the measures to be implemented. HACCP programs will need to be followed for five (5) years more to determine costs of the program. Educational programs designed for consumers starting at the grade school level, as well as educational programs designed for all food workers throughout the food production chain, will also help offset implementation costs.

Application to Raw Meat and Poultry. The Codex "General Principles for the Establishment and Application of Microbiological Criteria for Foods" (Codex, 1981) state that a microbiological criterion should be established and applied only where there is a definite need and where it is both practical and likely to be effective. The presence of various pathogenic bacteria on raw meats and poultry is primarily a result of their incidence in the live animal rather than as a result of inferior hygiene. The occurrence of these pathogens in raw meat and poultry cannot be entirely prevented by the application of strict sanitary hygienic principles. In addition, the distribution of pathogens in raw products is extremely variable, severely limiting the degree of confidence of a sampling plan to indicate the absence of a particular pathogen in a lot. Consequently, application of microbiological safety criteria for raw meat and poultry is inappropriate at this time.

Enterobacteriaceae have been frequently used in the industry as indicators of degree of hygiene during slaughter/dressing procedures. These organisms do constitute part of the raw product microflora after slaughter and dressing; however, their presence

is due to unavoidable fecal contamination and they do not necessarily provide any information regarding the presence of pathogens. Even without examination for pathogens or indicator organisms, it is logical to assume, based upon the knowledge of conventional slaughter/dressing procedures, that some fecal contamination is inevitable and that pathogenic bacteria may be present on raw products. A Food and Agricultural Organization/World Health Organization working group on microbiological criteria for foods (FAO/WHO, 1979) concluded that the number of indicator organisms in raw meat neither reflects adherence to a code of hygienic practice nor indicates presence or absence of pathogens. Therefore, criteria for raw meat and poultry products based upon indicator organisms were not considered to be justified by this group.

Microbiological monitoring of the product and the processing environment can be used to determine the effectiveness of processing methods that are designed to manage microbial contamination and growth. Aerobic plate counts (APC) can be used to monitor these procedures and Good Manufacturing Practices, and criteria based upon such examinations are a valuable aid in establishing quality control programs. While these criteria may be effective for evaluating processing conditions in-house, because of the perishable nature of the product it is probably not possible to set APC limits for criteria to be applied at the retail level or port of entry. In 1973, the state of Oregon set microbiological standards for fresh and frozen red meat at the retail level and revoked the standards four years later because:

- The standards were unenforceable and created a general adverse reaction,
- There was no evidence of reduction of foodborne disease or improvement in quality characteristics of the meat, and
- The standards may have created erroneous consumer expectations of improved quality and decreased hazard.

Application to Fully Processed, Ready-To-Eat Meat and Poultry Products. Microbiological criteria can be appropriately used to evaluate the microbiological quality of raw materials, to evaluate the effectiveness of equipment sanitation, and to determine the microbiological condition of the freshly processed product. (Based upon the critical control point of the process being verified, either a quality or safety criterion may be applied.) Baseline information for these evaluations must be established by the processor if useful limits are to be established. In some instances, a particular fully processed, ready-to-eat product may have been determined to be a significant vehicle for foodborne disease (i.e., *Salmonella* in cooked uncured meats, *Staphylococcus aureus* enterotoxin in fermented sausages). Microbiological criteria applied at the processing plant are recommended in these situations. In most cases, application of microbiological criteria to any of these products after they have entered trade channels is of little value.

The safety and quality of commercially processed foods is primarily a result of the treatments they receive and the restriction of post-processing recontamination. The perimeter of safety provided through traditional processing methods is very wide and greatly reduces opportunities for survival or growth of microorganisms. Control of these processes through programs such as the (HACCP) system is the only logical way to assure the safety of the food supply.

Conclusions

Microbiological criteria may be used as a means of monitoring critical control points in a HACCP system. However, effective monitoring most often involves the use of physical and chemical tests as well as visual observations to confirm the successful application of a process capable of eliminating microbiological contamination. Microbiological criteria may also be used independently of HACCP to determine the

ultimate acceptability of a food or process. The presence of various pathogenic bacteria on raw meats and poultry is primarily a result of their incidence in the live animal rather than as a result of inferior hygiene. Although the occurrence of these pathogens in raw meat and poultry cannot be entirely prevented by the application of strict sanitary hygienic principles, raw product can be rendered safe through proper cooking. Consequently, this makes the application of microbiological safety criteria to raw products inappropriate, whereas, in applying microbiological criteria to fully processed, ready-to-eat foods, they can be appropriately used to evaluate the microbiological quality of raw materials, to evaluate the effectivess of equipment sanitation, and to determine the microbiological condition of the freshly processed product. To be effective, a criterion must attain its stated objective. A standard must demonstrate the elimination or reduction of foodborne disease. Basic principles regarding the development and application of microbiological criteria must be followed if criteria are to meaningfully contribute to food protection. The education of food handlers, from farm workers to the consumers, is vital to application and success of HACCP programs.

Table 1

Plan stringency (case) in relation to degree of health hazard and conditions of use[a].

Type of hazard	Conditions in which food is expected to be handled and consumed after sampling, in the usual course of events[b]		
No direct health hazard	*Increase shelf life*	*No change*	*Reduce shelf life*
Utility (e.g., general contamination, reduced shelf life and spoilage)	**Case 1** 3-class n = 5, c = 3[c]	**Case 2** 3-class n = 5, c = 2	**Case 3** 3-class N = 5, c = 1
Health Hazard	*Reduce hazard*	*No change*	*Increase hazard*
Low, indirect (indicator)	**Case 4** 3-class n = 5, c = 3	**Case 5** 3-class n = 5, c = 2	**Case 6** 3-class n = 5, c = 1
Moderate, direct, limited spread	**Case 7** 3-class n = 5, c = 2	**Case 8** 3-class n = 5, c = 1	**Case 9** 3-class n = 10, c = 1
Moderate, direct, potentially extensive spread	**Case 10** 2-class n = 5, c = 0	**Case 11** 2-class n = 10, c = 0	**Case 12** 2-class n = 20, c = 0
Severe, direct	**Case 13** 2-class n = 15, c = 0	**Case 14** 2-class n = 30, c = 0	**Case 15** 2-class n = 60, c = 0

[a]Adapted from ICMSF (1986).

[b]More stringent plans would generally be used for sensitive foods destined for susceptible populations.

[c]n = number of sample units drawn from lot; c = maximum allowable number of positive results.

Appendix

OVERVIEW PAPERS

Traditional Postmortem Inspection

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I have chosen to present and discuss with you the topic of traditional postmortem inspection. I intend to make this presentation fairly short since this is a topic with which the majority, if not all of you, are very familiar. What I would like to do is briefly put forth a viewpoint on the following four questions:

1. What is traditional inspection and what is its history and philosophy?

2. Who uses traditonal inspection and does it differ substantially among countries (e.g., industrialized versus less developed)?

3. What are the strengths and weaknesses of traditional inspection? How good is it for identification of conditions of potential public health significance?

4. What barriers exist to modifying or replacing traditional inspection (e.g., domestically, internationally) with a more food safety oriented inspection system (e.g., QC, HACCP, risk-based approaches)?

What is traditional inspection and what is its history and philosophy?

Laws related to meat hygiene go back a long time in history. In Canada (New France), there were laws in effect in 1707. Other legislature was passed in the 1800's, but modern traditional meat inspection laws in North America primarily date from 1906 in the United States and 1907 in Canada. These laws related meat inspection to public health initiatives. The U.S. promulgated its legislation shortly after the publication of Upton Sinclair's best seller, *The Jungle.* This book depicted the poor hygienic conditions existing at the time in packing plants in the U.S.

Jeremy Rifkin, in a more recent book entitled *Beyond Beef,* compares the present situation with that of 1906, and concludes that the situation has not really changed.

The promulgation of the Meat Inspection Act in Canada is a reaction to the introduction of legislation in the U.S. The Meat Inspection Act was and still is, a trade act.

The type of inspection prescribed by these two acts was related to diseases of public health significance common at that time such as tuberculosis and cysticercosis.

Traditional inspection is an organoleptic inspection, in other words based on visual, palpation, incision, and olfaction techniques. The principles to be employed in the examination are very well enunciated in the book, *Food Animal Pathology and Meat Hygiene,* by Drs. Herenda and Franco, and I would like to quote them here.

- Make full utilization of visual, incision, palpation, and olfaction techniques.
- Observe all obvious lesions and associate the observations with a tentative diagnosis.
- Classify the lesions into one of two major pathologic categories—acute or chronic.
- Determine whether the condition is localized or generalized. If it is generalized, determine the extent of systemic changes in other organs or tissues.
- Correlate the pathology observed with the state of nutrition (condition) of the carcass, the age of the animal, breed, and other husbandry characteristics.
- Correlate colour abnormalities of tissues and exposed bone surfaces to both the primary and secondary pathologic processes.
- Determine the impact and significance of primary and systemic pathology and the relevance to major organ systems, especially the liver, kidneys, heart, spleen, and lymphatic system.
- Coordinate all the components of history, antemortem, and postmortem findings to arrive at a final diagnosis.
- If a diagnostic impasse exists, submit samples to the laboratory for diagnostic support.

You will note that the use of laboratory diagnostic is a last resort. The diagnostic has to be based on visual signs. One could relate these procedures to a more modern approach, i.e., HACCP. In HACCP, CCPs and CCLs are evaluated by quick, visual means that have been established using lab analysis as a base. As you can see, history has a tendency to repeat itself.

The purpose of the postmortem examination is, of course, to sort out the normal from the abnormal, and when the abnormal is encountered, to attempt to reach a diagnosis of the cause. Once the cause has been determined, a decision on the fitness of the meat from the carcass for human consumption must be taken and a suitable disposition made.

There are five principles in the disposition process.

1. Removal and condemnation of diseased or abnormal tissue.

2. Determination of acute versus chronic and localized versus generalized conditions and the consequent effect on the suitability of the carcass for human food.

3. Assessment of conditions resulting in the derangement of body functions; for example, icterus resulting from parasitic obstruction of the bile ducts.

4. The likelihood of the carcass containing substances injurious to human health, such as antibiotics or other harmful residues.

5. The elimination of offensive or repugnant conditions of the meat, which reflects the standards established by society. This obviously varies from country to country.

Having established a general philosophy for traditional inspection wherever meat inspection is performed, consideration needs to be given to the next question.

Who uses traditional inspection and does it differ substantially among countries (e.g., industrialized versus less developed)?

Organoleptic meat inspection is utilized by most countries. The major meat trading countries perform the inspection in very similar ways, and the disposition criteria are basically the same in these countries. However, the disposition of carcasses may vary from country to country depending on the willingness of consumers to accept what may be substandard meat. Meat products falling into this category are normally not exported but consumed domestically. Modifications to the procedures do occur where a particular disease or condition is present that requires additional procedures to enable the inspection staff to better detect it.

The traditional meat inspection procedures are required as the standard meat inspection system for the international meat trade. In April 1993, the Codex Committee on Meat Hygiene attended by representatives from 40 countries or international organizations finalized the draft Revised Code for Ante-mortem and Post-mortem Inspection of Slaughter Animals and for Ante-mortem and Post-mortem Inspection of Slaughter Animals and for Ante-mortem and Post-mortem Judgement of Slaughter Animals and Meat which details these requirements.

The generally accepted traditional postmortem inspection procedures are not utilized universally, even in industrialized countries with considerable resources. I am sure that large quantities of noninspected meat are consumed by the human population in many countries. This meat may constitute a considerable health risk. However, recent history has demonstrated that even fully inspected meat may also represent considerable public health risk.

What are the strengths and weaknesses of traditional inspection? How good is it for indentification of conditions of potential public health significance?

Traditional organoleptic postmortem inspection has been around for a long time and will probably be around for a long time to come. It does an adequate job of detecting carcasses affected by conditions with symptoms and pathology that are visible to the naked eye or can be detected by smell or touch. It has been refined somewhat over the years, and there are specific examination procedures for detecting common zoonoses with good reliability.

In many countries, continued improvements in the health status of livestock destined for slaughter has resulted in proportionately fewer and fewer animals going to slaughter that have these conditions or diseases. Meat, however, does represent another threat to human health when animals with zoonotic infections that present no visible lesions are presented for slaughter. The inability of traditional postmortem inspection to detect food-borne microbes of public health significance that inhabit the skin, lymph nodes, and gastrointestinal tract of healthy animals, together with the subsequent spread of these organisms during the slaughter and dressing process, is a critical weakness. Additionally, traditional postmortem inspection is a labour-intensive operation that places practical limits on line speed and industry's ability to produce. From a regulatory resource point of view, its efficiency is dependent on the efficiency of the establishment. These two factors are becoming more and more important at a time of resource restraints in government operations.

An additional concern is the perception held by some consumers that because every carcass is organoleptically inspected, it is safe. Liability of government agencies involved is also a major concern.

What barriers exist to modifying or replacing traditional inspection (e.g., domestically, internationally) with a more food safety oriented inspection system (e.g., QC, HACCP, risk-based approaches)?

The use of the traditional inspection system in international trade is a barrier to trade. In recent years, some of the rigidly prescribed specific carcass or viscera examinations have been studied by various countries to determine their applicability to their specific animal disease situation. A good example of such an exhaustive study was conducted in New Zealand on lamb inspection by Drs. Hathaway and McKenzie. Studies of this type, which are essential to the modification of inspection procedures and techniques utilizing modern scientific principles, are expensive and time-consuming to conduct. They are increasingly more difficult to conduct due to a lack of resources, both at the government and at the industry level. The introduction of new concepts and the development of inspection mechanisms to adequately deal with the invisible threats to public health require an international research and development effort. The very competitiveness of the international meat trade is both a barrier and an opportunity—a barrier in the sense that technical barriers to trade still occur, and an opportunity in that international cooperation is becoming more and more essential in the maintenance of the viability of the industry. Public concerns, especially with respect to food safety and animal welfare, are international and require international cooperation to resolve.

In conclusion, traditional meat inspection is a relic from the past and it needs to be changed. The reasons for such a change are obvious, and I have mentioned them earlier. Let me reiterate some of them.

1. The diseases for which this inspection system has been designed have been eradicated in a great number of countries.

2. The invisible threats, i.e., *Salmonella, E. coli,* etc., cannot be detected by traditional inspection.

3. Traditional meat inspection gives the consuming public a false sense of security and brings into focus the liability of government agencies involved in food inspection.

4. Traditional meat inspection is resource-intensive. In an environment of deficit and budget constraints, we need to conduct a very serious cost/benefit analysis of the present system.

5. The rigid application of archaic inspection procedures by some trading blocks has a trade-distorting effect.

Preharvest Pathogen Reduction Efforts in Denmark

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Introduction

In Denmark, meat and poultry inspection has been implemented in a very traditional manner since the 1890's—providing consumer protection against parasitic diseases such as trichinosis and infectious diseases such as tuberculosis, brucellosis, and anthrax. In addition, the meat inspector has remained alert for signs of animal diseases such as foot and mouth and classical swine fever (Animal Health and Disease Control Position in Denmark—List of Diseases). Every individual animal is inspected alive in the holding pens. After slaughter, the carcass is palpated and the lymph nodes and organs are incised to inspect for pathological lesions.

This type of traditional inspection in Denmark cost 1$/pig, 5$/cow, and 0.055/chicken. At least 80% of the money is spent on activities conducted at the slaughterline. Studies have demonstrated that this type of inspection provides little protection to the consumer against modern foodborne diseases.

Consumer protection policy must change to concentrate on residues, chemical contaminants, zoonoses, and specific bacteriological problems. The latter is particularly significant because of long storage periods of meat products in a chilled condition. The meat inspector must continue to maintain a vigilance for dangerous animal diseases. In addition, he/she should be able to assist the producer by feedback of information about defects/diseases in the animals, even if these are not of public health interest.

Modernizing Meat Inspection

During the past several years, the Danish Ministry of Agriculture (Veterinary Directorate, Meat Inspection Service), in close cooperation with the meat and poultry industry, has been working to change the policy in meat inspection to obtain (at a minimum) improved consumer protection, improved public knowledge of health status and the zoonotic status of food producing animals, and reduced expenditure on ritual inspection work with increased attention given to the points mentioned above.

A report concerning poultry was issued in 1985 and the necessary legal changes were implemented in 1991. EEC Directives following the same principles should be implemented in all EEC member states by the end of 1993. A report concerning red meat inspection was issued in January 1991, and is being implemented at the moment. Some of the suggestions from the Danish reports are built into the existing EEC Directives: 91/497 (fresh meat), 92/5 (meat products), 92/116 (poultry meat), and 92/117 (zoonoses).

The main principle in the changes has been to extend the knowledge about the meat products to cover all steps: ''From stable to table''. Only by obtaining knowledge about all stages in the production will it be possible to give reasonable guarantees of product safety to the consumer.

Another principle in the changes is to acknowledge that the production of broilers and pigs in Denmark has become industrial: the farmer has changed to a producer. Most of the diseases are of no concern to the consumers but are flock/management problems, usually not even problems of individual slaughter animals. The feed conversion ratio is stressed to the maximum when a 1800 gram chicken is produced in 35 days. The production is based upon a very delicate balance of biological systems which causes problems where one would not expect: e.g., in broilers, changing the size of feed pellets with no change of constituents may cause mass death in a production; deaths caused by failure of a ventilation system for a few hours or a hot summer period demonstrates that these production animals are not able to resist environmental changes. They are bred for rapid growth, not for a ''natural life''.

As far as consumer protection is concerned, the individual animal is clinically healthy at slaughtering but may create a risk to public health because of the presence of zoonotic agents brought into the slaughterhouse with the animals or spread by cross-contamination during operations. The official meat inspection policy must change according to the

changes in production patterns to be able to counteract consumer threats.

An Example: Poultry Inspection in Denmark

The 110 million broilers slaughtered annually are produced by 320 producers, all large operations making 6 rotations per year (all-in/all-out). Until 1992, meat inspection was done solely at the slaughterhouse. The live birds were "inspected" in the transport cages. Every bird was "inspected" after slaughter by veterinarians or trained technicians supervised by the veterinarian at a line speed of 6000/hr. Random sampling for residues was performed, but no knowledge of the production site was available for the chief veterinarian at the slaughterhouse to be used as a basis for decisions. The chief veterinarian had no database/official knowledge and no reporting system, at least not formally.

As of January 1992, poultry inspection has been begun by a veterinarian, employed by the meat inspection service, performing an inspection of every flock at the poultry house 3-5 days prior to delivery for slaughter. Currently, we have 6 full time "AM veterinarians" who are employed and equipped with government cars, radios, and fax machines to do the AM inspections. The inspector registers information on feed, weight gain, production time, additives, medications used, environmental problems in the house, floor covering conditions, feather appearance, etc. (See Figure 1). In advance of the AM veterinarian's visit to the poultry house, 16 birds from each flock are examined at the State Veterinary Laboratory and tested for the presence of *Salmonella,* which at the moment seems to be the most interesting zoonotic agent. *Campylobacter* might be the next. The AM veterinarian is obliged to give all the advice possible on management, disease control, etc., to the producer during the visit. In addition to obtaining information to be used for AM inspection, this on-farm visit facilitates rapid reaction to animal health problems in this country.

The AM inspector telefaxes his findings to the chief veterinarian at the slaughterhouse, who is informed about the *Salmonella* status and problems that have developed during the production period of the flock. The chief veterinarian decides if the flock (normally 50,000 birds) can be slaughtered normally or must be delayed to avoid contamination of *Salmonella*-free birds slaughtered on the same day. He/she also decides if it is necessary to collect specimens for testing of residues of medications or other contaminants. The postmortem results are reported back to the producer, the AM veterinarian, and the Meat Inspection Service to be utilized in improving future production results.

After inspecting the first few hundred carcasses at postmortem, the usual procedure is to allow company-employed personnel, trained by and supervised during the work by the chief veterinarian, to complete the postmortem inspection on the remainder of the flock. This allows the meat inspectors to have sufficient time to concentrate on general hygiene and other inspection duties. Using HACCP principles, the slaughter lines and cutting operation are regularly examined for *Salmonella* and *Campylobacter*. A training program on hygiene for all employees given by the local veterinarian is part of the modernizing scheme.

The Danish government strongly supports a *Salmonella* reduction program initiated by the poultry industry in the beginning of 1989. The reason for this support is obvious: In the beginning of this program more than 70% of the broilers delivered for slaughter were positive for *Salmonella*. Many of the positive birds had been infected by the feed, but obviously others were infected vertically by breeding. The program has been rather successful. The birds currently being delivered to slaughter are contaminated at a level of 10-15%. Our goal is to obtain less than 5% infected birds and no *S. enteritidis* or *S. typhimurium*. We hope to cope by the spring of 1994.

Another Example: Pork and Beef Inspection in Denmark

18 million pigs are produced by 30,000 producers (16 million by 8,000 larger producers). 800,000 cattle are produced by 30,000 producers. Meat inspection takes place in the slaughterhouse beginning with AM inspection at reception of the animals and ending with re-inspection of the meat upon delivery to export or the home market. HACCP, training, registration of pollution, etc., has been implemented, but due to Danish demands for inspection intensity (veterinarians and technicians) more than 80% of the expenditure is spent on slaughterline inspection.

The spring of 1993 has been very interesting for the pork producers and the Meat Inspection Service. In the middle of May, the municipal food inspection service in Copenhagen discovered that a small slaughterhouse, not approved for export to the USA, delivered meat that was heavily contaminated by *S. infantis* to the Copenhagen Market. At the same time, the Health Authorities demonstrated an increase in the number of reported cases of *S. infantis* in humans and predicted that the salmonellosis could become an epidemic. Fortunately, this incident stopped rapidly because the Veterinary Directorate was able to find the 3-4 large suppliers of fattened pigs to this slaughterhouse and stop them from delivering additional animals. Obviously, corrective actions of all possible kinds were taken. The reason for the sudden incidence was a strike on all the large cooperative slaughterhouses, pressing the small to deliver more than their capacity, in combination with 3 weeks of very hot weather.

One obvious problem in this case was that the municipal laboratory in Copenhagen used the tabloid press and morning newspapers to give reports of their findings to the Veterinary Directorate.

ANTE MORTEM CONTROL IN POULTRY

BROILERS

Farmer	Reg.no.	Rotation	House.

Hatchery	Hatchingflock	No.of chickens.	Salmonellastatus,hatchingflock
Date of delivery:			

Age weeks	No.of dead	Average live weight	Medical treatment		
			Date	No.of days	Drug ,dosage/route
1					
2					
3					
4					
5					
6					
7					

Days from cleaning to disinfection:	Disinfectant:
Days from disinfection to delivery	Presence of Alphitobius diaperinus: yes no

Feed mill:	Dept:	Approved: yes no
Coccidiostats:	Growth promotant:	
Delivery of finisher, date:		
Salmonellastatus, lab.result, carcass specimen:		Expected date of slaughter

Lab. investigations:	feed	carcass	swabs	other (specify)
Litter:	dry	wet	hard	Plumage: clean filthy
Clinical symptoms:	respiratory	skin	legs	diarrhea
Comments:				

HEALTH CERTIFICATE AM-CONTROL **AM-CONTROL HAS TODAY INSPECTED ABOVE FLOCK**

No. of birds_____ Age_____ Abattoir:_____

In the light of inspection and information obtained, the flock can be slaughtered as planned_____ extra inspection staff required_____

DATE:_____ VETERINARY OFFICER (SIGNATURE)_____

Figure 1

So the newspapers asked the Minister of Agriculture (and the Minister of Health): "What are you doing about this situation"?

The situation speeded up some of the initiatives already taken: During the last year, as part of the program mentioned above and described in the report from January 1991, the Veterinary Directorate together with scientific agencies and industry has prepared a modernization plan. A very important part of the program is concerned with the presence of zoonotic agents in animals delivered for slaughtering and how to handle producer sites delivering clinically normal animals but hosting *Salmonella* species or other agents that may endanger consumers.

For many years, the pig-producing industry has operated a SPF program. As a result of the general development—and of the public interest for the moment—it is of considerable commercial interest to produce HPF-animals. The meat producers obviously will benefit, or possibly only survive, by producing animals free of pathogens (SPF = specific pathogen-free animals, HPF = human pathogen-free animals).

The Veterinary Directorate, supported by regulations to be issued by the Minister of Agriculture, has started screening of 19 pig producers delivering more than 10,000 pigs/year, followed by screening of 1500 producers delivering more than 2000/year, and continuing with the rest of the producers. The examination is done by sampling caecum content and making laboratory examinations for *Salmonella*. The work is done as part of the chief veterinarian's responsibility as part of the meat inspection work. The laboratories are approved by the Veterinary Laboratory.

In the case of clinically diseased animals (salmonellosis), the producer is subject to restrictions by the local government veterinarian and all clinically safe pigs are delivered with a pass to the chief veterinarian at the slaughterhouse. Pigs from these producers are slaughtered last in the week or the day using very strict slaughter hygiene, rejection of red offal, etc. 20 swab samples from the meat surface (1400 sq. cm.) are examined for *Salmonella* by each delivery. Carcasses are retained until the slaughterhouse has demonstrated 5 times that it is capable of slaughtering without transferring *Salmonella* from the intestines and throat to the meat.

The information about the situation at the production sites is at the moment collected centrally, but the plan is to have the chief veterinarian at the slaughterhouse use the information to decide the fate of all animals delivered for slaughtering. As mentioned, the industry cooperates willingly on the scheme because the benefit is obvious when selling on an international meat market.

All slaughterhouses have final products examined (25,000/year) for *Salmonella* every two weeks, so the development can be followed. In addition, the municipal services are sampling a large number every month.

As far as beef production is concerned, we have not had any serious problems with the presence of *Salmonella*. However, the sampling of final products allows us to follow the situation very closely.

Animal husbandry controls in Denmark are based on a regulation dated February 18, 1993. In accordance, all animals must be marked by ear-tags before 30 days from birth and before they leave the farms of origin. Fattened pigs delivered to slaughter can be marked by needle tattooing. Any imported animal must be ear-tagged by a special red ear-tag designed by the Veterinary Service. The Ministry of Agriculture is currently setting up a central register for animal husbandry, so all animals will be registered in Denmark in the very near future.

Conclusion

The Danish Veterinary Directorate, in close cooperation with the meat and poultry industry, has been working to modernize meat inspection. Using this type of approach, we feel reasonably sure to be able to give guarantees to consumers and up-to-date information to the producers.

An Overview of Risk Analysis and Meat and Poultry Inspection

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Meat hygiene consists of three major activities: postmortem inspection, monitoring and surveillance for chemical hazards, and maintenance of good hygienic practice throughout all stages between slaughter and consumption of meat. Risk analysis will be of increasing importance to these activiites as a means of facilitating the distribution of both preharvest and postharvest inspection resources proportional to the likelihood of public health and animal health hazards, establishing internationally harmonised standards and specifications that are consistent and science-based, and improving the safety and wholesomeness of meat and meat products in local and international trade.

Risk analysis in the area of food safety is most developed with respect to chemical hazards, and least developed with respect to microbiological hazards (Hathaway, 1993). The purpose of this overview paper is to introduce risk analysis by posing ten questions on its general application to meat and poultry inspection. Several aspects of these questions currently remain unanswered, and it will be the task of the Congress workshop to discuss new approaches. A review paper (Attachment I) provides detailed information to assist these discussions.

What are the elements of risk analysis and how can they be applied to meat and poultry safety?

Risk analysis is an applied rather than a theoretical discipline and the three main elements are risk assessment (RA), risk management (RM), and risk communication (RC).

RA is the primary scientific process and is regarded as the estimation of the likelihood (probability) and severity (magnitude) of harm or damage resulting from exposure to hazardous agents or situations. Scientific value judgements and policy choices are inevitably involved at some decision points in the RA process and these ''RA policy'' issues should have clear policy guidelines.

RM is concerned with development and selection of policy options for the purpose of decisionmaking, and the implementation of the regulatory programme that is developed from the RA. A range of methodologies are available for risk analyses involving human values, e.g., ''zero risk'', threshold, comparative, or balancing risk standards. In discussing risk analysis, it should be recognized that while uniform principles of RA and RM can be pursued, uniform conventions are not necessarily advisable in deciding what level of proof is acceptable for policy purposes (Ashford, 1988). Three general models of risk analysis are described in Attachment I.

Recognition of RC is a vital part of the risk analysis process (see below).

Health RA is a specific application of RA that has almost exclusively been used to investigate chemical and radionuclear hazards. In this sense, risk is the likelihood of an adverse outcome when a person(s) is exposed to a particular concentration or dose for a specific period of time, i.e., risk is a function of exposure and absorbed dose. Health RAs are typically divided into four activities:

(1) Hazard identification—the qualitative indication that a substance/agent may adversely affect human health;

(2) Hazard characterisation (including dose-response assessment)—the qualitative and quantitative evaluation of the nature of the adverse effects;

(3) Exposure characterisation—the qualitative and quantitative evaluation of the degree of human exposure likely to occur;

(4) Risk characterisation—integration of the above steps into a quantitative estimation of the adverse effects likely to occur in a given population, to be used in decisionmaking.

Specific application of RA is needed to evaluate each of the classes of hazards associated with meat and poultry products. The general principles of RM and RC apply to all classes of hazards, and RM risk

standards such as as-low-as-reasonably-achievable (ALARA) can be used to adopt "zero risk" as an ideal but balance the ideal against "reasonable" cost limits on the resources needed for the obtained level of safety. RM decisions on the optimal use of inspection resources should not seek to eliminate all hazards, but remove all major hazards and ensure that any residual hazards are minor in nature and exist at a prevalence that constitutes a "negligible" risk to the consumer.

What do we understand about "hazards" in meat and poultry?

Inspection programmes are primarily engaged to ensure that meat and poultry products are "safe and wholesome". In the case of raw meat and poultry, this is only a qualitative measure of freedom from hazards to human (and animal) health. Antemortem and postmortem meat inspection cannot guarantee freedom from all clinically or grossly detectable abnormalities, and monitoring programmes have limited ability to detect randomly occurring violative levels of chemical hazards. More importantly, some degree of inadvertent microbiological contamination is inevitable in the slaughterhouse/processing environment.

It is clear that meat and poultry represents a mixed system in terms of "hazards", and all must be considered in a risk analysis approach to meat inspection. Postmortem meat inspection procedures are applied to remove grossly detectable conditions: those of potential public health and animal health importance, and those aesthetic defects that are unacceptable to the consumer. Chemical residues and contaminants of potential public health importance may be introduced at any stage in the meat or poultry production system and specific monitoring and surveillance programmes are necessary for this class of hazards. Inadvertent contamination with microbiological hazards (either preharvest or postharvest) that are not detectable at postmortem inspection requires specific control programmes, and it is probable that this class of hazards presents by far the greatest source of risk to human health in meat and poultry products.

The relationship between the total cost function for controlling hazards and the total benefit function to the consumer will be different for each class of hazards.

How can risk assessment be applied to the safety of meat and poultry products (for biological, chemical, and physical hazards)?

Chemical Hazards. RA in one form or another is relatively well established in the development of standards and guidelines for chemical substances in meat and poultry and this is largely consequential to the application of "risk analysis" in the general area of chemical contamination of foods. Thus health risk analysis for chemical hazards is considered first in this overview discussion.

The safety assessment of chemical substances is largely based on the results of high-dose toxicological studies in laboratory animals. The no-observed-effect-level (NOEL) approximates a threshold level below which an adverse health effect will not ordinarily occur. The dose-response part of the RA is based upon the scaling up of animal data to humans. In most evaluations, the NOEL is divided by a safety factor so as to compensate for uncertainties in the scientific process, and the "safe" dose is established as an acceptable daily intake (ADI). This dietary intake is not expected to result in any adverse health effects over the lifetime of an individual in the general population. In the case of contaminants inadvertently present in food, "provisional tolerable daily (or weekly) intakes" that denote permissibility rather than acceptability are calculated.

Safety evaluations carried out in this manner cannot be regarded as quantitative measure of risk; the ADI end-point is derived by imposing a specific margin of safety. However, the use of safety factors avoids the need to set a numerical "acceptable level of risk".

Quantitative risk assessment (QRA) has a specific application in the safety evaluation of chemical substances that have carcinogenic potential. QRA utilises a mathematical extrapolation to fit the observed data (usually derived at high-dose levels) to the expected dose-response at low-dose levels. The outcome is an estimation of a "virtually safe dose" that correlates with an excess over background risk that is acceptable to society, e.g., 1×10^{-6} cases of cancer per lifetime of daily exposure.

The safety evaluation of chemical substances in food is further described in Attachment I, with specific reference to the elements of risk analysis that are included in safety evaluations. "RA policy" decisions embedded in safety evaluations are of particular note, e.g., the application of arbitrary safety factors to the NOEL represent specific mechanisms to create conservative margins of safety proportional to the development of a "no risk" level of exposure.

The methodology that has evolved in "risk analysis" of chemical substances needs to be well understood when developing risk analysis methodology for other classes of hazards. Particular points for comparison are:

(1) Setting of tolerances for most hazardous chemicals in food generally has been based on the tenet that the dose, not the substance, is the poison. This principle embodies the concept of threshold doses for toxicants;

(2) There is a primary need for both toxicity data and exposure data. "Safe" levels are assessed as a function of exposure to a particular *dose* for a *specific* period of *time,*

(3) When predicting the level of human exposure, most safety evaluations for chemical substances in food relate the ADI to the best available food intake information. In some cases, the exposure assessment includes a detailed scenario set, e.g., estimated maximum daily intakes of pesticide residues based on information on maximum residues in the edible portions of the particular commodity, corrected for the reduction/concentration of residues on preparation, commercial processing, and/or cooking;

(4) The safety factor approach does not involve quantitative determination of an ''acceptable level of risk,'' whereas QRA for carcinogenic toxicants does derive a quantitative estimate of risk;

(5) RM decisions in many cases will take into account a qualitative benefit/cost analysis of RM options. As examples: MRLs for contaminants as recommended by the Joint Expert Committee on Food Additives (JECFA) include consideration of toxicity, the economic cost of achieving MRLs, and the technological feasibility of monitoring different MRLs; and pesticides are registered in the United States on the basis that they do not cause ''any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide''.

Abnormalities Detectable at Postmortem Inspection. Most inspection programmes apply the large majority of their resources to continuous postmortem meat and poultry inspection. The United States National Research Council, in reviewing changes to traditional postmortem inspection procedures for poultry and swine between 1979 and 1983, could find no evidence that the changes in procedures were likely to diminish protection of public health (Anonymous, 1985a). However, it was also found that there was ''no clear evidence that the traditional inspection procedures were based on objectives and criteria that relate to public health. In the absence of a systematic accumulation of data on which to base a complete technical analysis, no overall assessment of risks and benefits could be made''.

Subsequent research into postmortem inspection procedures for a variety of species in several different countries has verified the general applicability of these comments (Hathaway and McKenzie, 1991). An RA approach can be used to address these problems and facilitate the proportional allocation of resources according to level of risk (Hathaway and McKenzie, 1989; Anonymous, 1992). It is noteworthy that risk analyses of postmortem inspection programmes will inevitably have to address aesthetic ''hazards'' as well as biological, toxicological, and physical hazards. Many postmortem inspection procedures function to detect and remove aesthetic hazards, and in many on-line inspection situations it is difficult to differentiate between true safety hazards and aesthetic ''hazards''.

As with all risk analyses, a number of ''RA policy'' decisions are inherent to the RA model. With the realisation that even high-intensity routine inspection procedures are neither 100% sensitive not 100% specific, RM decisions should focus on the *comparative* performance of the different procedures (particularly nondetection rates) under test (Hathaway and Richards, 1993). It is suggested that a framework for RM decisions on the comparative performance of different postmortem inspection programmes should include:

(1) Demonstration that any potential increase in public (and animal) health risks on a case-by-case basis is ''effectively zero'' using an ALARA standard;

(2) Application of an ALARA standard for any differences in aesthetic risks;

(3) Identification of scenario sets where appropriate;

(4) Judgement by expert arbitration as a procedural standard;

(5) Qualitative integration with RAs for other components of the inspection programme.

Exposure of the human population to ''hazards'' in meat that should have been detected by the postmortem inspection procedures under investigation is very dependent on the particular processes and conditions that apply prior to human consumption. Construction of a detailed scenario set and calculation of the likelihood of each possible risk scenario can be achieved by several statistical methods. PC software programmes such as @RISK (Palisade Corporation, New York) are now available for this purpose.

RM decisions must include consideration of fair distribution of risks and in this respect, demonstration of the equivalence of different national postmortem inspection programmes presents a particular case. Comparative RAs that demonstrate equivalent performance ensure that the bearers of any risk, i.e., the consumers, are not involuntarily exposed to any increase in risks brought about by the producers of the meat or poultry products under inspection.

A detailed description of RA and RM aspects of risk analysis for postmortem inspection procedures is given in Attachment I.

Microbiological Risks. Quantitative evaluation of the microbiological safety of foods has primarily been dependent on the establishment of microbiological criteria as standards, guidelines, or specifications. The principles for the establishment and application of microbiological criteria for foods include elements of risk analysis, and a direct and statistically based link is usually required between the adequacy of sampling plans and the severity of any microbiological criteria imposed.

However, there is considerable debate over the application of microbiological criteria to classify food as microbiologically acceptable or unacceptable and many standards and guidelines have proven to be impractical. This is certainly the case for raw meat and poultry (Anonymous, 1985b).

The problems associated with risk analysis of foodborne microbiological disease are very different from risk analysis for other classes of hazards, and to date the development of an appropriate RA model has been inhibited by lack of information and lack of a detailed conceptual framework. Microorganisms multiply and die and the biological interactions are complex. In the case of meat and poultry, the characteristics of contamination during slaughter and dressing dictate the character of the initial microflora on the carcass, but this can be markedly modified by subsequent events. Additionally, there are marked differences in the virulence and pathogenicity of animal and environmental strains for humans, and the interaction of host and microbiological pathogens is very variable. Even if a minimum ''threshold infective dose'' is assumed, the above variables illustrate the difficulties in constructing a detailed and scientifically justified exposure scenario set. Also, it is readily apparent in microbiological systems that a prediction of exposure should not lead to an automatic assumption of risk (Skinner, 1992).

The best probability estimates of exposure would come from a detailed epidemiological study on the human population of interest at the range of doses or exposures of interest. Unfortunately, such studies rarely exist, and estimates of risk are only described in terms of relative or attributable risk.

Another approach would be to experimentally construct a numerical dose-response curve for each potential pathogen that may be present in the final product and attempt to characterise risk in these terms. However, experience in ecological RA would suggest that irrespective of the general unavailability of the quantitative data (human or animal), developing this additive organism-by-organism approach may be difficult (Tiedje and others, 1989; Skinner, 1992). Despite the complex challenges of microbiological RA, a quantitative model has been developed for waterborne disease in the United States (Regli and others, 1991).

A consideration of the animal health guidelines for import risk analysis (Anonymous, 1993) provides an interesting comparison. Only a limited number of well-documented animal diseases need to be considered and considerable quantitative data is available on the prevalence and biology of the aetiological agents. Currently, RAs for microbiological hazards in raw meat and poultry cannot draw on equivalent human data and this makes microbiological RA a difficult proposition. In addition, a microbiological RA for meat and poultry at a particular time of importation/ distribution is only meaningful if the subsequent measures that are taken maintain the same microbiological quality.

HACCP systems for assuring the safety of meat and poultry products contain some important elements of microbiological risk analysis (Biss and Hathaway, 1993), and regulators should consider parallel development of such systems when developing microbiological RA models (see below).

What is the best way to identify and categorise by severity the risks of different hazards associated with foods (ranking or prioritising hazards)?

Risk is a function of the likelihood and severity of an outcome. However, preceptions of the ''severity'' of foodborne health risks commonly include concurrent consideration of the severity of health effects in the individual, the frequency of cases, and the cost (treatment, control, and monitoring).

''Severity'' in a broad sense can be used to rank ''hazards'' according to level of concern/need for evaluation, and can be used as a parameter affecting ''RA policy'' and RM decisions.

Chemical Hazards. Several methods have been used to rank chemical hazards according to ''severity''. Structure/activity relationships may be useful for predicting the toxicity of some compounds; however, systematic use has serious shortcomings. Notwithstanding this, structure/activity relationships and level of exposure have been used to set levels of concern and identify types of studies required (Anonymous, 1982).

The United States Environmental Protection Agency uses a qualitiative weight-of-evidence classification for suspected carcinogens so as to rank likely carcinogenic activity in humans. This classification usually dictates where RA resources should be directed, and chemicals placed in category A or B normally will undergo a QRA that utilises upper-bound estimates of risk and worst-case default options (Anderson, 1988). In this system, ''severity'' is equated to a high probability of the chemical being carcinogenic, and the effect of this judgement is more rigorous RA and more conservative RM.

The United States Food Safety and Inspection Service's (FSIS) Compound Evaluation System is used as a component of the National Residue Programme to rank chemical substances for residue health risks (several classes ranging from high health hazard to negligible health hazard). This qualitative ranking is combined with a qualitative exposure assessment to determine monitoring needs.

The ''severity'' of chemical hazards in health effect terms is primarily addressed in safety evaluations by the differential use of safety factors applied to the NOEL. As examples, the normal safety factor may be increased by irreversible embryotoxic effects, teratogenic effects, and neurotoxic effects produced in the experimental animal system. Conversely, the safety factor may be decreased if toxicity and dose response effects in humans are known, and these warrant a reduction.

JECFA acknowledges that the use of standardised safety factors is a crude procedure with respect to different health end-points; however, ''the nature of the effect and a determination of its significance are often implicitly considered by scientists when reviewing the data''. JECFA also acknowledges that there may have been undue emphasis in the past on consideration of carcinogenic versus non-carcinogenic health end-points. Paustenbach (1989) considers that newer methods to identify chemicals that pose a significant carcinogenic, developmental, or reproductive hazard to humans will allow ''more enlightened approaches to interpreting the significance of animal bioassay data and provide much more defensible hazard identifications''.

Differential application of safety factors according to severity of health effects results in lower ADIs and will lead to decreased exposure in the general population. By increasing safety margins, there is a qualitative expectation of a decreased probability of expression of ''severe'' disease. It should be noted that the same mechanism is applied in response to age-related effects such as accommodating the special sensitivity of young children; is this also perceived as a ''severity'' issue?

Thus ranking systems for ''severity'', and inclusion of ''severity'' as a health effect parameter affecting ''RA policy'' and RM decisions, either include a consideration of exposure or result in standards that decrease exposure to ''severe'' hazards. Characterisations of ''severity'' in this way must be used carefully. The general risk model multiplies probability by magnitude (character, extent, timing) to gain an estimate of risk, but the same value can result for risks that have very different characteristics.

Grossly Detectable Abnormalities. Gross abnormalities detectable at postmortem inspection can be caused by zoonotic and non-zoonotic infectious agents. Unlike the general case for chemical hazards, any expression of human disease due to abnormalities in the former category is not a function of accumulative exposure over time. Most abnormalities are in the latter category and as such their importance is limited to aesthetic unacceptability (or presenting an animal health risk). Gross abnormalities therefore present a range of RM options, and each type of hazard has to be evaluated on a case-by-case basis (Hathaway and McKenzie, 1989).

In general terms, the ''severity'' of risks associated with grossly detectable abnormalities will be ranked or characterised in broad categories. The primary goal of postmortem inspection is to remove all grossly detectable hazards that have zoonotic potential, and some abnormalities will be pathognomonic for known zoonotic agents. These should be identified in the hazard identification, and technically justified and feasible inspection procedures put in place to detect these hazards even if the prevalence (and hence human exposure) is very low. Unlike chemical hazards, the potential for postharvest cross-contamination of meat and poultry products further underpins the goal of detecting all abnormalities that constitute known public health hazards.

RM decisions would be unlikely to allow a change in inspection procedures if there was an increased nondetection rate of abnormalities of known zoonotic importance using a proposed new procedure. Nothwithstanding this, RM may consider ''negligible'' differences in the performance of different inspection procedures when the prevalence of hazards is very low, or the true sensitivity of all feasible inspection procedures is low (Attachment I).

Many abnormalities detectable at postmortem inspection will have a low probability of containing zoonotic agents, e.g., nonspecific abscessation, and present a very low probability of transmission to humans exposed to the product (Hathaway and McKenzie, 1990). These abnormalities can be considered to be of much lesser ''severity'' in terms of human health, and this qualitative judgement may include consideration of likely human exposure. Risk analysis of a postmortem inspection programme may support proposals for new procedures if changes in nondetection rates for these abnormalities of low ''severity'' are small.

Detection and removal of aesthetic hazards is primarily a quality issue but this has traditionally been a regulatory function, e.g., for nonzoonotic cysticercosis. Aesthetic abnormalities are not of concern with respect to public health. RM options for different inspection procedures will consider their practicability and cost versus the comparative nondetection rates and their likely effect on consumer acceptibility and market access.

Microbiclogical Hazards. Although RA biases may operate in both directions, regulatory RM decisions are usually conservative and overstate the risk. RM judgement problems (Ashford, 1988) are exacerbated in microbiological risk analysis because of marked uncertainties with respect to the ''severity'' of the risk, or the economic and technological feasibility of regulatory controls. Aversion to respective commitment of either Type I errors (unjustifiable regulation to control a ''hazard'') or Type II errors (failure to justifiably regulate an identified hazard) will alter as a conceptual framework for microbiological RA evolves, and increased knowledge provides a more scientific base for judgements on regulatory options.

Possible outcomes of microbiological contamination are true (rather than predicted) exposure, infection, acute and/or chronic disease, and death. Secondary spread of infectious agents also is an issue, and the RM decision may have to be between ''zero risk'' and ''total risk'', e.g., an animal pathogen that if introduced will spread throughout the animal population. The relevance of these different categories in terms of characterising ''severity'' in microbiological RA has yet to be established.

The FSIS Compound Evaluation System used to rank chemical residues may be useful as a model for ranking microbiological hazards (R. Brewer, personal communication). It is suggested that a function of different qualitative categories of health effects (morbidity, mortality, number of cases, characteristics of clinical illness) and different qualitative categories of potential exposure will provide a useful ranking for pathogens in meat and poultry. However, estimating true exposure according to different scenario sets for meat and poultry products presents considerable problems, especially in the absence of information on infective dose ranges.

One of the most important uses of microbiological risk analysis is likely to be in the development and application of regulatory and industry systems for control of unseen microbiological contamination during slaughter, dressing, and further processing of meat and poultry products. In this respect, RM decisions on the average allowable bioload of contaminants of gastrointestinal (or other) origin may represent the most important short-term advance (Attachment I).

What kind of processes are most important to assess?

This question is readily answered. In the ideal situation, all processes from "farm to plate" need to be included in a flow diagram from which an overall risk analysis of public health hazards can be initiated. The HACCP approach provides a systematic framework for identification of critical control points (CCPs) and establishment of critical limits and monitoring systems, and will be discussed in detail elsewhere in the Congress.

Development of HACCP systems for meat and poultry products needs to be closely aligned with development of risk analysis methodology for microbiological hazards if the system that is applied is to be scientifically justifiable. In the case of slaughter and dressing, initial research in New Zealand suggests that organoleptic parameters may not be related to microbial loads on carcasses and monitoring of HACCP CCPs in these terms could be fallacious (Biss and Hathaway, 1993). If the additive marginal risks that microbiological contamination imposes at different CCPs are to be ranked and evaluated, together with an evaluation of the cost-benefit of reducing these risks, detailed microbiological data are required.

With respect to risk analysis of foodborne hazards other than grossly detectable abnormalities, there should be a specific consideration of:

(1) Pathways and processes for contamination in the live animal;

(2) Pathways and processes for contamination of the product during processing, storage, distribution, preparation for consumption, etc.

(3) Fate of the contaminant at each of the above steps, and the true level of human exposure that is likely to ensue.

As examples of the wide diversity of processes that may be important in meat and poultry hygiene, many potential pathogens are found in the gastrointestinal tract of slaughter animals on the farm of origin and result in cross-contamination in the slaughterhouse; *Campylobacter* spp. survive well on poultry carcasses because of the process step of water immersion chilling; and high numbers of *Listeria monocytogenes* are most commonly associated with inadequate refrigeration of contaminated cooked processed products. Surveillance data indicate that the incidence of foodborne disease outbreaks caused by poor hygienic practice during food processing is very much lower than that caused by mishandling foods in food service establishments or in the home. However, there is obviously a potential for affecting much larger numbers of people in the former case.

Is it possible to estimate reasonable infectious dose ranges for pathogenic microorganisms? If not possible, what are practical alternatives?

There is a dearth of human experimental data infectious on dose ranges for pathogenic microorganisms, and such data is unlikely to significantly increase in the future (Skinner, 1992). Little work has been done to validate the use of experimental animal models for predicting dose/response curves in humans, and available data suggests that the biological complexity of host/pathogen interactions would make extrapolation of animal data to humans much more uncertain than is the case for chemical hazards. Some epidemiological reports document that high infectious doses for particular foodborne pathogens are necessary to produce clinical disease, e.g., 10^5 cells per gram for *Bacillus cereus,* but the infectious dose for other pathogens such as *Salmonella, Campylobacter,* and *Listeria* spp. must be very low.

Human experimental data can be interpreted as a dose/response relationship in which it is assumed that one cell can establish infection (or disease) and the probability of acquiring an infection (or expression of disease) increases as the level of exposure of the individual increases. Thus the dose/response data could provide an estimate of a range of risk values associated with different exposure levels within a short time-frame. Alternatively, a threshold approach can be taken, where it is predicted that a certain minimum infectious dose is needed to establish infection (or disease). This would be the highest dose that an individual could be exposed to without resulting in the undesirable health effect.

The quantitative RA model developed for waterborne disease in the United States (Regli and others, 1991) was based on a number of dose response relationships derived with a range of microorganisms used in human experiments. A number of assumptions were made, including those of

homogeneous distribution in water, average daily water intake, and an ''acceptable'' level of risk. Such work was only possible because of the low pathogenicity of the microorganisms involved and is unlikely to be repeated for microbiological hazards in meat and poultry.

In the absence of quantitative dose/response curves, microbiological RA must rely on qualitative RA that incorporates hazard identification, hazard characterisation, exposure characterisation, and risk characterisation. Even in application of this qualitative framework, there are large gaps in knowledge. Any hazard identification will be far from complete, as new information on foodborne disease is constantly emerging, and the number of known pathogens associated with unseen microbiological contamination is steadily increasing. An evaluation of the nature of the adverse effects may require information on a number of different end-points (see above) for the setting of ''RA policy'' and making RM decisions. Determining the degree of human exposure likely to occur from specific meat- and poultry-borne pathogens presents the greatest difficulties, and adequate methodology has yet to be developed for this purpose. Human epidemiological studies can provide some information but generally are beset by insensitive monitoring systems and a range of confounding factors.

Consideration of alternatives to the use of dose/response curves in microbiological RAs for meat and poultry products begs the question: are we in fact looking for a new way to assess the need for microbiological criteria? When setting microbiological criteria, there is explicit consideration of evidence of hazards to human health; microbiology of the raw material; effect of processing on the microbiology; likelihood and consequences of microbial contamination and/or growth during subsequent handling, storage, and distribution; category of consumers at risk and potential for abuse at the consumer level; reliability/practicability of analytical methods, and benefit/cost ratio associated with the application of the criterion (Anonymous, 1985). This qualitative reasoning contains many of the elements of a qualitative microbiological RA. In applying this reasoning to safety evaluation of microbiologically sensitive foods, it has been found in most instances that control of hazards should be through application of Codes of Practice (including HACCP) rather than through establishment of microbiological criteria.

Microbiological RA for unseen contamination on raw meat and poultry may find a useful comparison in the use of ''presence'' and ''severity'' for determining different categories of risk in the establishment of microbiological criteria (Anonymous, 1985). With respect to ''presence'', specific microorganisms, groups of microorganisms, or toxins can be grouped in broad categories: not be present at all; present in only a limited number of samples; or present as less than a specified number or amount in a given quantity of food. With respect to ''severity'', the broad categories are: moderate with limited spread; moderate with potentially extensive spread; and severe.

What kind of communication efforts contribute to a more effective food risk analysis programme?

There is a large array of channels through which information about risks can be communicated. These range from warning labels on individual product wraps to government-sponsored meetings involving all interested groups. Evaluation of risk by the public is often wider than that of the ''experts'', and is more likely to include concurrent consideration of issues such as voluntary/nonvoluntary exposure, familiarity, fairness, possibility of alternatives, and potentially catastrophic effects. The mass media focus on the same concerns when reporting on public health risks.

Increased interest in RC with respect to public health has several underlying factors, including an increase in ''transparency'' and ''right-to-know'' laws, increased public concern about food safety, and a loss of trust in government and industry (Covello 1992). Vested interest groups can readily exploit the latter two factors if attempting to undermine particular aspects of regulatory inspection programmes.

The problems and difficulties of effective RC can be organised into four categories (Covello, 1992):

(1) Characteristics and limitations of scientific data about risks;

(2) Characteristics and limitations of government officials, industry officials, and other spokespersons in communicating information about risks;

(3) Characteristics and limitations of the media in reporting information about risks;

(4) Characteristics and limitations of the public in evaluating and interpreting risk information.

Improvements in RC not only depend on improvements in the above-mentioned problem areas; the actions of the regulatory agency itself must also improve. Collaboration with organisations and individuals that are perceived to be trustworthly and credible is an important policy decision. Goals such as education and sharing of information can only be achieved once trust and credibility have been established. Unfortunately, prospects for developing high levels of public trust at the government level are modest, especially in the short term and on a national or global level. (Covello, 1992).

The mass media play a critical role in RC, and the characteristics and limitations of these vehicles in reporting information about risks are generally well understood. This is a consequence of the difference in definition of objectivity between science and journalism. Science adheres to evidence in the search for truth, whereas in the latter case, objectivity represents balance in reporting conflicting claims,

i.e., reporters cover viewpoints, not ''truths'' (Anonymous, 1986b). An effective RC strategy that involves the media must incorporate an understanding of their particular constraints and needs (Sandman and others, 1987).

In general terms, the public determines an ''acceptable'' level of risk not only on the level of the risk but also according to their own values, sense of risk, and stake in the outcome. As values and opinions differ, debates about risks are often debates about values, accountability, and control. Covello (1992) makes the important observation that in the public view, efforts to make a risk fairer, more voluntary, controlling mechanisms more inclusive of the public, etc., can be as important in determining an acceptable level of risk as are efforts to reduce the level of the risk. This further emphasises the integral role of RC as a part of risk analysis.

Risk comparisons can play an important role in RC by putting complex probability-based information into a more intuitively meaningful form (Wilson and Crouch, 1987). Thus they can assist in setting priorities and determining which risks are acceptable to the public, but application of risk comparisons to risks having different qualities are open to question.

Problems also may arise in achieving integrated and effective RC between risk assessors and nonexempt decision makers responsible for RM. It is desirable that an infrastructure exists so that risk managers fully understand the technical and scientific aspects of the RA, and can make an objective evaluation.

It is clear from recent experiences in RC on a world-wide basis that regulators must actively combat the public's desire/perception of ''zero risk'' for raw foods, and the unrealistic expectations of the effectiveness of regulatory action. Regulatory authorities have avoided challenging the ''zero-defect'' concept of the consumer in the past, largely because they themselves have had very little scientific data with which to quantify their empirical knowledge. If regulatory authorities are to genuinely engage in a scientific and risk-based allocation of inspection resources, they will need to develop particular skills in communicating to the public the residual risks inherent in all components of any meat and poultry inspection programme.

Is it reasonable to categorize risks by populations susceptible to different risks?

Special consideration of increased risks borne by sub-sets of the general population is common in safety evaluations for chemical hazards in food. JECFA recognises different susceptibility given the same dietary intake, e.g., if very young children (less than twelve weeks) will be exposed, more extensive toxicological investigations are required and they must include evidence of safety in very young animals. Alternatively, larger safety factors can be applied to the NOEL for age-related effects if children are to be exposed to the hazard.

When predicting the level of human exposure, most safety evaluations for chemical substances in food relate the ADI to the best available food intake information. JECFA estimates exposure by using three general methods:

(1) *Per capita,* the exposure level if the chemical substances were equally distributed across the population;

(2) *Dietary food surveys,* including data for subpopulations with differing susceptibility to adverse health effects;

(3) *Market basket (total diet) surveys,* involving analysis of a diet representative of the general population.

National authorities may reduce ADIs if dietary intake data reveals that subpopulations consume large amounts of a particular food product. Given the uncertainties common to RA of chemical hazards, consideration of some subpopulations when setting ADIs may not be justified if the increase in susceptibility is small, or only a qualitative evaluation of any increase has been made. The wide inter-individual differences in food items selected and consumed means it is inevitable that some individuals in the general population will exceed the ADI to some extent for some period of time, and ADIs should generally be set for levels of consumption that are two to three times above the average level (Renwick, 1992).

In the case of infectious agents, health-disadvantaged subpopulations may have a significantly increased susceptibility to infection and disease. Accommodation of this special susceptibility in microbiological RA should be based on detailed hazard and exposure characterisation data, but this is unlikely to be available. RM decisions will need to incorporate appropriate risk standards.

How can all stakeholders be included in the risk analysis process?

Inclusion of all stakeholders in the risk analysis process requires standardised and regular procedures to consult with all stakeholder groups to ascertain their perception of the risks involved, and their views on RM options (Brunk, 1992). There is a need for open and effective instruments of communication (both internal and external to the regulatory agency), and full descriptions of the implications of RM options need to be available to stakeholder groups. These requirements are obviously integral to an effective RC strategy as described above.

The regulatory agency also must have a coherent and politically effective regulatory policy. There must be consistent application of methods and risk standards to similar situations, and the underlying philosophy of RM needs to be generally supported

by stakeholder groups. Bruck (1992) considers a politically effective RM regime will utilise RC to achieve:

(1) Establishment of effective channels for incorporating public attitudes and perceptions of risk into risk policy;

(2) Publicising and explaining of the rationale behind RA and RM regulatory policies;

(3) Public announcement to stakeholders of the risk standards and management policies that are being applied.

How should risk analysis efforts in food safety be harmonised on the international level?

RA is now a regulatory principle in a number of countries and international trade in meat and poultry products will increasingly depend on harmonised approaches to risk analysis. In this respect, the report of the 38th Session of the Codex Executive Committee (1991) stated that all relevant Codex committees should describe the basis of the RA methods used in arriving at their recommendations, guidelines, or standards. This process is underway (Hathaway, 1993). Additionally, expert international committees must carry out safety assessments in a consistent, transparent manner and strive for harmonised methodology (Herrman, 1993).

With the intent that national measures be based on international standards and guidelines wherever possible, the GATT Uruguay Round draft Decision on Sanitary and Phytosanitary Measures (SPS) is particularly important as a vehicle for harmonisation. The SPS states that "contracting parties shall ensure that their SPS measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations".

Individual governments duplicate a lot of the effort expended by international agencies in evaluating food chemicals, and it has been noted that some national resources could be diverted to international agencies if governments were convinced that the international evaluations were scientifically valid, consistent with government principles, and took their particular governments' concerns into account (Herrman, 1993). The increased availability of resources would increase overall cost-effectiveness and facilitate removal of artificial barriers to trade, while assisting developing countries that have inadequate resources to carry out evaluations on a national basis. Irrespective of the above goal, national government agencies need to more actively participate in the development of international standards, and consider international standards to a greater extent when developing their own standards.

A number of national and international organisations have published guidelines for RA of chemical hazards. These guidelines are usually considered as working documents that foster consistency in decision-making and help to resolve scientific controversy. Unfortunately, no such guidelines are available for RA of hazards that are grossly detectable at postmortem inspection of meat and poultry, or for microbiological RA.

Current international activities in the RA of all classes of hazards are summarized in Attachment I. In the case of microbiological RA, several countries have recently embarked on studies to gather microbiological baseline data on dressed carcasses as a first step to provide quantitative input to an RA model.

Veterinary animal health authorities and the Office International des Epizooties (OIE) are actively developing import risk analysis in the field of animal health. Guidelines for import RA include a consideration of adverse events of both animal and public health importance but it is noteworthy that the OIE guidelines limit RM to "the identification, documentation and implementation of the measures that can be applied to reduce the risks and their consequences". In addition to the need for consistent application of risk analysis methodology in the domain of both veterinary public health and animal health, the cost-effective allocation of regulatory resources in the preharvest area of food production will increasingly demand an integrated risk analysis approach.

International efforts to harmonise risk analysis methodology will also need to be reflected in national law. Food law usually documents the general requirements for food safety; regulations provide the detail required for specific applications. Regulations must become flexible enough to allow application of risk analysis so that science-based rule-making can follow.

This Congress will provide an important opportunity to set up networks for harmonisation of risk analysis for different classes of hazards that may be present in meat and poultry products. RA for these hazards is newly emergent, but is crucial if meat and poultry inspection systems are to meet modern meat hygiene goals.

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Attachment 1

Risk Analysis and Meat Hygiene

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Summary: *Meat hygiene consists of three major activities: postmortem inspection, monitoring and surveillance for chemical hazards, and maintenance of good hygienic practice throughout all stages between slaughter and consumption of meat. Risk analysis is an applied science that is of increasing importance to these activities as a means of facilitating the distribution of both preharvest and postharvest inspection resources proportional to the likelihood of public health and animal health hazards, establishing internationally harmonised standards and specifications that are consistent and science-based, and improving the safety and wholesomeness of meat and meat products in local and international trade.*

Risk analysis in one form or another is well-developed with respect to establishing standards and specifications for chemical hazards, and methods for risk analysis of postmortem meat inspection programmes are beginning to emerge. However, risk analysis of microbiological hazards in meat and meat products presents particular difficulties. All areas of application currently suffer from a lack of international agreement on risk assessment and risk management methodology.

KEYWORDS: Meat hygiene—Risk analysis—Veterinary public health—Postmortem inspection—Chemical hazards—Microbiological hazards.

Introduction

Foodborne disease is generally recognised as a major human health problem and an important cause of decreased economic productivity in both developed and less developed countries. Despite this, there is very little information available on the true level of exposure of specific populations to potential hazards, particularly in the case of bacterial diseases transmitted by consumption of meat and meat products. Attempts to quantify human health risks consequent to exposure to foodborne hazards largely rely on extrapolation of information gained from individual disease outbreak investigations to the population at large.

In the case of meat hygiene, the qualitative recognition that unseen microbiological and chemical contamination rather than grossly apparent abnormalities are now the most important sources of hazards to human health has led to increasing demands for a more systematic regulatory approach to combat these hazards. In particular, dependence on traditional meat hygiene programmes that focus the large majority of resources on routine ante- and postmortem inspection is now recongised as being inadequate (7, 12, 15, 19, 20, 53, 67, 77).

A wider recognition of the high level of complexity of food safety issues and increasing demands from consumers for maximum protection are other factors forcing regulatory authorities to adopt a more systematic and scientific approach to meat hygiene. Commensurate with these changes, protection of food from contamination, spoilage, and adulteration is no longer limited to being primarily a domestic issue; regulatory authorities must respond to increasing demands for facilitation of international trade.

Food safety goals. The food safety goals that are now being adopted by regulatory authorities profess to incorporate the overriding philosophy that resources should be allocated towards identifying and controlling those hazards that are of greatest public health importance and in doing so, there should be cost-effective allocation of those resources (7, 21, 24, 54, 55, 67, 79, 80). In reality, little scientific progress has been made to support this philosophy. Despite the resource-intensive nature of meat hygiene programmes, assessment of their overall benefit is still limited by the lack of systematic data on the various elements of meat hygiene as they relate to public health, and by the inherent difficulty in relating findings during inspection to end-points in terms of public health.

In the medium term, regulatory authorities need to develop science-based decision-making criteria that justify the chosen allocation of resources and underpin the overall conduct of meat hygiene programmes. In particular, normative (value-laden) decisions that have been made in the absence of good scientific knowledge need to be reassessed, and coherent strategies for control of hazards in the preharvest area of production need to be developed.

Although widely applied in the assessment of engineering and nuclear risk, formal risk analysis is relatively new to the field of food safety. Risk analysis of meat hygiene programmes is the primary focus of this paper; however, the discussion has general application to other raw foods. Risk analysis will be used to reshape existing meat inspection programmes, as well as being a vehicle to address technical issues that affect international trade in meat and meat products. In the field of animal health, risk analysis will more likely be focused in the latter area of activity: assessing (and managing) risks associated with the international movement of animals and animal products.

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Risk analysis. Risk analysis is based on an amalgam of scientific and technical information, and social and political policy decisions. Thus it is an applied rather than a theoretical science (48). The elements of risk analysis are risk assessment (RA), risk management (RM), and risk communication (RC).

RA is the primary scientific process and is regarded as the estimation of the likelihood (probability) and severity (magnitude) of harm or damage resulting from exposure to hazardous agents or situations. In the ideal situation, the RA process would be restricted to the ''value-neutral'' (non-normative) assessment of purely objective scientific data generated from alternative courses of action.

Scientific value judgements and policy choices are inevitably involved at some decision points in the RA process. Thus scientific experts assembling RA data should be guided by clear policy directives when any value judgements affecting the outcome of the RA are made (33, 37, 63). Determining this ''RA policy'' is an interactive process and examples of decision points where policy guidelines are necessary are: range of hazards included in the primary hazard identification, judging the scientific adequacy of the data set that is available, treatment of uncertainty, and deciding on the statistical basis for the standard of proof. The treatment of uncertainty is an ''RA policy'' issue that has particularly important implications; should the ''worst-case'', ''best-case'', or mean of the range of uncertainty be chosen?

Health RA is a specific application which has almost exclusively been used to investigate chemical and radionuclear hazards. In this sense, risk is the likelihood of an adverse outcome when a person(s) is exposed to a particular concentration or dose for a specific period of time, i.e., risk is a function of exposure and absorbed dose (69). Health RAs are typically divided into four activities: hazard identification, hazard characterisation (including dose-response assessment), exposure characterisation, and risk characterisation (6, 11).

RM is concerned with development and selection of policy options for the purpose of decision making, and the implementation of the regulatory programme that is developed from the RA. The options that are considered may be quantified solely in economic terms and RM decisions made according to some risk balancing standard, e.g., the risk-cost benefit analysis producing the highest benefit/cost ratio. However, RM decisions often have to be made in the face of significant scientific uncertainty and the values that are considered may not be reduced to monetary values alone. Relevant social criteria concerned with issues of ''equity and ethics'' include standards of health, technological feasibility, social concerns, and politics (44, 78).

The likely distribution of risks and benefits is another key issue in RM decisions. As an example, economic benefits from more cost-effective production methods for a food commodity will predominantly accrue to the producers, whereas any increase in public health risks that could possibly result from the changes would be borne by the consumer. This also raises the question of who should provide the burden of proof of public health safety when a change in production methods is proposed: the producer of possible risks or the bearer of possible risks?

Risk managers must make a choice about what is an ''acceptable'' level of risk. The simplest technique is a risk-cost-benefit approach in those situations where all RM options can be reduced to, and quantified in, economic terms. Risk analyses involving human values will require use of other methodology such as threshold, comparative, ''zero-risk'', or as-low-as-reasonably achievable (ALARA) risk standards. The latter technique is useful in many public health situations and typically adopts the means of reduction of an identified risk that most effectively uses the available resources. In doing so, ALARA adopts ''zero risk'' as an ideal but balances the ideal against ''reasonable'' cost limits on the resources needed for the obtained level of safety (37).

Three general models of risk analysis can be recognised (6, 11, 37, 69): the ''one-stage'' model, the ''two-stage'' model, and the interactive model. The ''one-stage'' model attempts to reduce risk analysis to a purely technical exercise, integrating all aspects of RA and RM into one decision-making matrix based on a risk-cost-benefit standard.

The ''two-stage'' model demands clear functional separation of RA and RM and has emerged as a common regulatory principle in the United States (6, 11, 75). The RA stage is a purely scientific and technical exercise that attempts to deliver fully quantified assessments of risk to risk managers. The RM stage is concerned with deciding on an acceptable level of risk that is explicitly recognised as a value judgement.

The interactive model also identifies RA and RM as separate functions but recognises that the interactive normative decisions that determine ''RA policy'' must operate in tandem rather than sequentially (37). The same value choices underpinning the RM process should also underpin the ''RA policy'' decisions taken during the RA.

Recognition of RC is a vital part of the risk analysis process. The results of RA and RM need to be effectively communciated both within and between regulatory authorities and to the public. Formulation of regulatory policy should include representative consultations with public ''stakeholders'', and the basis for the RM decisions that are taken should be effectively disseminated in a ''transparent'' format to all interested parties.

Public health and animal health risk analyses share common principles (31,50) but the way in which an animal health risk analysis proceeds may be quite different. Quantitative information on the prevalence of a disease agent in the host population and the

probability of transmission is much more likely in cases of specific diseases of animal health importance compared with (often unspecified) diseases of human health importance. Additionally, RM decisions in animal health import risk analysis are likely to depend on the trustworthiness of information gathered in another country on an on-going basis, focus on means of reducing risks associated with imported animals or animal products, and be limited to estimating the probability of the hazard being realised rather than including an estimation of the severity of such an outcome.

In discussing risk analysis, it should be recognised that while uniform principles of RA and RM can be pursued, uniform conventions (such as levels of statistical significance) are not necessarily advisable in deciding what level of proof is acceptable for policy purposes (33). As an example, it may be appropriate to rely on ''most likely'' estimates of risk when evaluating a chemical that is essential to a beneficial societal acitivity (e.g., use of radionuclides in medicine), whereas a ''worst-case'' estimate may be appropriate when evaluating a nonessential chemical (70).

Why risk analysis in meat hygiene?

Meat hygiene programmes are primarily engaged to ensure that meat and meat products are ''safe and wholesome''. In the case of raw meat, this is only a *qualitiative* measure of freedom from hazards to human (and animal) health (51). Postmortem meat inspection cannot guarantee freedom from all grossly detectable abnormalities, and sampling programmes have limited ability to detect randomly occurring violative levels of chemical residues and contaminants. More importantly, some degree of inadvertent microbiological contamination is inevitable in the slaughterhouse environment.

Risk analysis provides a specific tool to assess the risks and benefits associated with a particular meat hygiene system. In this respect:

—''Risk assessment'' is now a regulatory principle in a number of countries and is increasingly being referred to in food safety legislation. RA and RM in public policy decision-making is probably most advanced in the United States, where Federal Regulations require that risk research define risk, consider its effects, identify target populations and provide some form of cost-benefit analysis (11, 16). Some statutes include consideration of risk-cost-benefit balancing (e.g., pesticides) whereas others specifically exclude this (e.g., disposal of hazardous wastes). Where approrpriate, a formal consideration of risks to occupationally exposed groups, the public, and the environment is being written into new EC directives, and Directive 80/391/EEC (1 January 1993) provides a general framework for risk and safety issues;

—Food law usually documents the general requirements for food safety; regulations provide the detail required for specific applications. However, the pace of change in food technology and scientific knowledge is now rapidly outstripping the rate of amendment of legislation, and regulations must be flexible enough to accommodate these rapid changes. Application of the principles of RA and RM provides the opportunity for flexible but science-based rule-making within a legislative framework;

—International agencies, in particular the Codex Alimentarius Commission (CAC), are undertaking an increasing role in developing standards and guidelines for food safety, leading to harmonisation of requirements governing world trade (27). The report of the 38th Session of the Codex Executive Committee (23) stated that all relevant Codex committees should be required to describe the basis of the RA methods used in arriving at their recommendations, guidelines, or standards;

—With the intent that national measures be based on international standards and guidelines wherever possible, the GATT Uruguay Round draft Decision on Sanitary and Phytosanitary Measures (SPS) states that ''contracting parties shall ensure that their SPS measures are based on the assessment, as appropriate to the circumstances, of the risks to human, animal, or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations'' (25). Evaluation of the ''equivalence'' of particular inspection programmes used by different trading partners will increasingly depend on risk analysis;

—The Hazard Analysis Critical Control Point (HACCP) approach to food safety is gathering momentum worldwide (20, 24, 41). The principles of RA and RM are primary elements in the design of HACCP systems and in the utilisation of the data generated by those systems for regulatory purposes;

—The public perception of food safety is often very different to that which is scientifically appropriate or even feasible. Well-structured research based on RA principles, coupled with effective RC, are needed to change this perception;

—Veterinary animal health authorities and the Office International des Epizooties (OIE) are actively developing import risk analysis in the field of animal health (31, 61). Guidelines for import RA include a consideration of adverse events of both animal and public health importance but it is noteworthy that the OIE guidelines limit RM to ''the identification, documentation, and implementation of the measures that can be applied to *reduce* the risks and their consequences''. In addition to the need for consistent application of risk analysis methodology in the domain of both veterinary public health and animal health, the cost-effective allocation of regulatory resources in the preharvest area of food production will increasingly demand an integrated risk analysis approach.

Postmortem Meat Inspection

Despite the fact that most meat hygiene resources are engaged in routine postmortem meat inspection

activities, there has been very little emphasis on gaining scientific evidence to link this function with measurable outcomes in terms of human health. Additionally, there has been little progress in tailoring inspection procedures to the spectrum and prevalence of the diseases/defects present in a particular class of slaughtered livestock from a specific geographical region (7, 49, 53, 55, 79). A RA model can be used to address these problems and facilitate the proportional allocation of resources according to level of risk (53, 57). In doing so, the performance and equivalence of different meat inspection systems also can be judged.

Risk assessment. In broad terms, the major ''hazards'' detectable at postmortem meat inspection are identified during observation of tissues. Following removal of the most important hazards, incremental benefits decrease as the level of inspection intensity increases. The optimum usage of postmortem inspection occurs when the incremental gain in benefits (in the broadest sense) equals the incremental increase in costs (73). Thus the optimal use of inspection resources does not eliminate *all* hazards, but removes all important hazards and ensures that any residual hazards are minor in nature and exist at a prevalence that constitutes a ''negligible'' risk to the consumer (57).

A number of studies have been conducted in recent years to evaluate particular postmortem inspection programmes (40, 49, 53, 66,67, 68, 79, 84). Each study has used different methodology and very few have assessed the true performance attributes of the procedures under investigation, even in those cases where the presence of a disease may constitute a specific zoonotic risk. In the absence of rigorous RA methodology, such studies leave regulatory authorities exposed to legitimate challenge if the outcomes have been used as the basis for RM decisions on the allocation of inspection resources. As an example, the US National Research Council reviewed changes to traditional inspection procedures for poultry and swine between 1979 and 1983 and concluded that the changes were unlikely to diminish protection of public health (7). However, it also concluded that there was ''no clear evidence that the traditional inspection procedures were based on objectives and criteria that relate to public health. In the absence of a systematic accumulation of data on which to base a complete technical analysis, no overall assessment of risks and benefits could be made''.

A well-designed RA model can provide a quantitative basis for comparative evaluations, thus delivering scientifically appropriate information for RM decisions. The four analytical steps of the general health RA model (6, 11) can be suitably modified:

—*Hazard identification:* All hazards that could be present in the tissues of interest and that could be detected by organoleptic inspection procedures need to be identified. ''Hazards'' in meat hygiene include public health hazards, animal health hazards, and aesthetic defects that are unacceptable to the consumer;

—*Hazard characterisation:* The dose/response relationships that are developed from laboratory animal trials to assess chemical hazards are inappropriate for the characterisation of gross abnormalities detectable at postmortem meat inspection. Therefore *all* conditions that may possibly be present in the final product and that can be detected by postmortem inspection procedures are considered;

—*Exposure characterisation*: Exposure of the human population to ''hazards'' in meat that should have been detected by the procedures under investigation is very dependent on the particular processes and conditions that apply prior to human consumption. Despite this, the ''worst-case'' exposure characterisation must assume that the consumer will be exposed to all hazards that are capable of being detected by organoleptic meat inpsection but which escape the inspection procedures in place. Thus the establishment of the performance attributes of individual procedures (sensitivity, specificity, nondetection rate) allow a quantitative characterisation of exposure. The nondetection rate can be defined as the proportion of abnormal tissues among those classed as normal by the individual procedure, and is equivalent to (1 minus the negative predictive value of the test) (57);

—*Risk characterisation:* A consideration of the difference between nondetection rates for all identified hazards for each procedure, together with a scientific assessment of the consequences of each difference, provides the basis for the risk characterisation. The investigator must consider the importance of all individual ''hazards'' that are missed during the application of particular procedures on a case-by-case basis. However, in the case of tissues that are not destined for human consumption, the only hazards of significance are those that serve as an indicator function for other tissues, or those which may have implications for animal health;

The design of field trials incorporating the above elements has been previously described (53, 57). As a working example, the application of an RA model to evaluate all postmortem inspection procedures for the viscera of lambs slaughtered in New Zealand utilised field trials conducted in 3 export slaughterhouses and involved more than 963,000 comparative evaluations (53). This has resulted in a new national code of meat inspection for these tissues. The quantitative methodology used in the RA model provides the basis for determinations of equivalence between the New Zealand and other national codes of ovine meat inspection.

Risk assessment policy decisions. The RA model quantifies the precise nondetection rates that accompany different postmortem inspection procedures for a specific class of livestock, and

provides the basis for the establishment of an acceptable defect level based on a scientific assessment of the likely public health, animal health, and aesthetic risks. Adequacy of design can be assessed by reference to established scientific principles. The only likely sources of contention in the RA model should be the RA policy decisions inherent in that model.

Selection of sampling parameters are RA policy decisions that are primarily scientific value judgements. Samples must be representative of the population to which the conclusions are to relate and must include enough samples to enable definite conclusions to be reached as to the consequences of any change in inspection procedures (57). The level of residual risk that is not addressed by the model also depends on sample size. A fixed sample size, *say S*, has a 95% chance of including any abnormality that occurs at a prevalence of 1 in S/3, approximately (47). Therefore a sample size of 30,000 has the capability of limiting the chance of nondetection of an unidentified hazard to less than 1:10 000 with 95% confidence, and this would represent a practical compromise between the desire to detect all abnormalities that could possibly occur at very low prevalences, and the practicality of conducting large-scale field trials.

Other RA policy decisions include the statistical choice for comparison of the outcomes of different inspection procedures. Some studies have used tests of statistical significance to decide on equivalent performance but although superficially attractive, they provide only limited information on the comparative performance of the procedures (57). The most rigorous approach upon which to base RM decisions is to consider the worst cases included in the confidence intervals for the nondetection rates for each procedure.

Risk management. Decision-making criteria for establishing an acceptable level of risk for postmortem meat inspection programmes may be complex. With the realisation that even high-intensity routine inspection procedures are neither 100% sensitive nor specific (53, 66,68, 73), RM decisions should focus on the *comparative* performance of the different procedures under test. It is not technically feasible nor cost-effective for current meat inspection systems to eradicate *all* potential hazards from fresh meat produced for human consumption. Thus a ''zero risk'' approach to RM is inappropriate. A framework for RM decisions on the comparative performance (and equivalence) of different postmortem meat inspection programmes should include:

—Demonstration that any potential increase in public health risks on a case-by-case basis is ''effectively zero'' using an ALARA standard;

—Application of an ALARA standard for any differences in aesthetic and other risks;

—Identification of ''scenario trees'' and the likely modification of exposure to identified hazards, where appropriate;

—Judgement by expert arbitration as a procedural standard;

—Integration with RAs for other components of the meat hygiene programme;

—Consistent and credible risk analysis policy which is communicated to all interested parties.

The detection of any abnormalities of potentially severe human health, animal health, or aesthetic importance is an obvious prerequisite of any inspection regime but application of high-intensity procedures to detect *all* abnormalities of trivial importance is not defendable if resources are to be allocated according to areas of greatest risk. ALARA adopts ''zero risk'' as an ideal but balances the ideal against ''reasonable'' cost limits on the resources needed for the obtained level of safety. ALARA does not demand the exact quantification of risks and benefits in terms of a single denominator, and would be sensitive to the uncertainties that are implicit in veterinary public health risk analyses. As such, ALARA is a reasonable compromise between the often unachievable demands of ''zero-risk'', and the practical and social/political difficulties of a quantitative risk-cost-benefit approach (37).

An important issue in RM is a consideration of scenario trees for meat and meat products. The scenario tree starts with an initial event and charts the functions that can affect the outcome of the initial event. Construction of a scenario tree collectively describes the risk model, and calculation of the likelihood of each of the risk scenarios (and their aggregation into an overall quantification of risk) can be achieved by several statistical methods. The use of probability density formats is gaining in acceptance (60) and in this case, quantification of each scenario parameter depends on expressing each numerical value as a probability curve against all possible values. PC software programmes such as @RISK (Palisad Corporation, New York) can use more elemental probability distributions, e.g., triangular distributions based on minimum most likely and maximum estimates, to carry out iterative calculations for RA.

Constructing scenario trees for risk analysis of raw meat and meat products is not a simple task, and should be undertaken on a case-by-case basis. Some process interventions remove public health hazards, e.g., freezing of meat to specified temperatures to kill parasitic cysts (59), whereas microbiological hazards may be potentiated by product abuse prior to consumption. In contrast, some aesthetic hazards may be rendered unrecognisable by further processing interventions. Difficulties in determining true levels of human exposure to microbiological hazards that may be associated with grossly detectable abnormalities (including amplification by cross-contamination), as well as the likely magnitude

of effects (see later discussion), are compounded by the wide variation and unpredictability in events between processing and consumption for different meat products. In the absence of adequate dose-response data and the wide variability in outcomes in different individuals if transmission of an infectious agent occurs, RM will usually be limited to decisions based on the probability alone of the hazard(s) being realised under different operating systems.

It is likely that postmortem meat inspection activities that detect and remove grossly abnormal tissue contribute relatively little to safety in modern meat production systems (7, 15, 52, 54, 56). Unfortunately there is no RA model to assess the relative importance of these activities with those of process control systems that attempt to minimise inadvertent microbiological contamination during slaughter, dressing, and further processing. In the absence of any systematic data on the public health impact of current postmortem inspection procedures for poultry in the United States, a major study by the National Research Council concluded that the primary focus on organoleptic inspection should be shifted to quality assurance systems for microbiological and chemical surveillance (15). In a New Zealand context, an extensive bacteriological survey of grossly detectable abnormalities in lamb viscera revealed very few bacteria of public health importance; a subsequent literature review indicated that almost all potential meatborne zoonoses would be the result of unseen contamination with enteric pathogens, many of which have high asymptomatic carriage rates (54).

International activities. The need for systematic risk analysis of postmortem meat inspection programmes is now widely recognised internationally. Despite being addressed in principle, there are few international initiatives to translate this principle into generally agreed risk analysis methodology. National initiatives have led to some changes in domestic programmes but there is a concern that inadequate methodology may lead to criticism of such changes in the future (7, 15, 52). The widely recognised need to accept the equivalence of different national programmes where warranted, and harmonise international requirements for trade, also suffers from the lack of international initiatives in developing risk analysis models.

The recent redrafting of the codes of practice on all aspects of meat hygiene by the Codex Committee on Meat Hygiene (28) incorporates general principles for a risk analysis approach but it is beyond the purvey of this committee to initiate a working group to develop specific methodology. Notwithstanding this, the CAC has asked that all relevant Codex Committees describe the basis of any RA methods they utilise (23). International agreement on risk analysis methodology is also implicit in the GATT Uruguay Round SPS Decision (25).

Risk analysis of any postmortem meat inspection programme would necessarily entail public recognition that some level of exposure to grossly detectable abnormalities is unavoidable. Regulatory authorities have avoided challenging the ''zero-defect'' concept of the consumer in the past, largely because they themselves have had very little scientific data with which to quantify their empirical knowledge. If regulatory authorities are to genuinely engage in a scientific and risk-based allocation of inspection resources, they will need to develop particular skills in communicating to the public the residual risks inherent in all components of any meat hygiene programme.

Chemical Hazards

Routine monitoring and surveillance for chemicals, contaminants, and residues in meat and meat products (''chemical substances'') constitutes a major element of meat hygiene programmes. Food additives will have been deliberately added during processing at levels up to those allowed by food standards whereas other chemical substances may have entered the food chain at any stage of production or processing.

Unlike the situation with on-line postmortem inspection, risk analysis in one form or another is relatively well established in the development of standards and guidelines for chemical substances in meat and meat products. This is largely consequential to the application of ''risk analysis'' in the general area of chemical contamination of foods, and the importance of meat as a dietary component in average daily food intake calculations. However, in some specialised applications in meat hygiene, e.g., residues of veterinary drugs, formal risk analysis is a relatively recent development.

Risk analysis of chemical hazards has primarily been used to establish maximum permitted limits in target tissues or meat products. In the international area, the CAC and its expert groups (the FAP/WHO Joint Expert Committee on Food Additives [JECFA] and the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment/WHO Expert Group on Pesticide Residues [JMPR]) have emerged as the most suitable bodies for facilitating the harmonising of food, health, and sanitary regulations for chemical substances worldwide (27, 65).

By comparison, the sampling plans for monitoring chemical substances in meat and meat products are rarely evaluated on a risk analysis basis. In the absence of 100% monitoring (c.f., postmortem meat inspection), the statistical adequacy of sampling plans is an essential component of a systematic risk-based approach. As a parallel activity, the scientific validity of regulatory responses when violative levels for specific substances are detected (domestically or at port-of-entry inspection) has rarely been subjected to risk analysis.

Risk assessment. Prior to toxicological evaluation, data is required on the chemical structure, stability, presence of impurities, and breakdown products of

the compound to be assessed. This data facilitates identification of the chemical to be used in animal toxicity tests, and the type of studies to be performed.

In general terms, the safety assessment of chemical substances in meat and meat products should contain the elements of the four analytical steps described for all health RAs (6). Differing methodologies have been developed in different countries but the safety assessment of all chemical substances is largely based on the results of high-dose toxicological studies in laboratory animals, and precepts about what might occur at lower doses (14, 62, 69, 75). Detailed descriptions of the methodologies that are used are widely available and the dose-response part of the RA is based upon the scaling up of animal data to humans. Relevant biological data include biochemical tests; acute and chronic toxicity studies; special studies, e.g., testing possible neurotoxic, reproductive, or mutagenic effects; and observations in man. Metabolic studies may be used to complement extrapolation of laboratory animal findings to man.

The no-observed-effect-level (NOEL) determined from laboratory animal studies approximates a threshold level below which an adverse health effect will not ordinarily occur (14, 16, 17). (This assumes that a threshold dose actually exists and no toxic effect will occur below this). In most evaluations, the NOEL determined in the most sensitive species is divided by a safety factor so as to compensate for uncertainties in the scientific process. However, a shortcoming of this step is the inability to take the shape or slope of the dose-response curve into account.

The ''safe'' dose is established as an acceptable daily intake (ADI) for a food and is expressed on a body weight basis. This dietary intake is not expected to result in any adverse health effects over the lifetime of an individual in the general population. In the case of contaminants inadvertently present in food, ''provisional tolerable daily (or weekly) intakes'' that denote permissibility rather than acceptability are calculated.

The total intake of a chemical determines exposure. For most safety evaluations of chemicals occurring in food, diet will constitute virtually the entire avenue of exposure. If a chemical is highly toxic but exposure is very low, the risk will be successfully ameliorated. In contrast, long-term dietary exposure to large amounts of a chemical of low toxicity may represent a significant level of risk. Information from national dietary intake studies (22) is used to evaluate whether a proposed maximum level for a chemical substance in a particular food is toxicologically supportable in terms of the cumulative intake in all foods.

Safety evaluations carried out in this manner cannot be regarded as a quantitative measure of risk. Although the approach contains some of the elements used in a formal health RA, the ADI end-point is derived by imposing a specific margin of safety. The use of safety factors has the advantage of preventing problems that may be associated with determining an acceptable level of risk against which a quantitative RA would have to be compared.

Evaluations of residues of veterinary drugs present a specific departure from the general methodology of safety evaluations of chemical hazards in food. Fixed assumptions are made about dietary intake and these are used to characterise the ADI (14). The number of tissues in which veterinary drug residues are found is limited, and intakes in the upper range limits for edible tissues (e.g., 300 g of muscle) are chosen. Maximum residue levels (MRLs) are calculated by using the ADI and the selected intake factors. Use of the drug according to good veterinary practice yields MRLs that are compared with the potential MRLs derived from the ADI.

True quantitative risk assessment (QRA) has a specific application in the safety evaluation of chemical substances that have carcinogenic potential. QRA begins with identification of those chemicals which may pose a human cancer or developmental hazard, and involves characterising the nature and strength of the evidence of causation (3, 70). Most methods use a ''weight-of-evidence'' approach and the classification will be of primary importance if it dictates the nature of the QRA to be carried out, e.g., chemicals placed in Group A and B by the United States Environmental Protection Agency (EPA) are always assessed using upper bound estimates of risk and worst-case default options (4). Chemicals placed in Group C are assessed on a case-by-case QRA basis.

QRA utilises a mathematical extrapolation to fit the observed data (usually derived at high-dose levels) to the expected dose-response at low-dose levels (2, 29, 30, 70). The available models evaluate the slope of the dose-response curve but are unable to take account of the biological factors that may modify the response at low levels, thereby having an influence on the calculation of excess lifetime cancer risks for humans. QRA also has been used in the United States as a method to develop cancer potency estimates (Q^*) (16), but this application is now controversial (70). The outcome of QRA for carcinogenic chemicals is to estimate a ''virtually safe dose'' that correlates with an excess over background risk that is acceptable to society, e.g., 1×10^{-6} cases of cancer per lifetime of daily exposure to the calculated amount of the chemical in foods.

While QRA methodology offers considerable potential for improving RAs, the current inability to reliably model the underlying biological mechanisms of carcinogenicity suggest limited usefulness. In this respect, recent availability of human epidemiological data indicates that in some cases the QRA dose-response model may grossly overestimate the acutal cancer risk (70), and in certain circumstances it has been suggested that application of the NOEL/safety factor approach would be a more rational approach to evaluation of nongenotoxic carcinogens (38).

Newer quantitative approaches include physiologically based pharmacokinetic models and biologically based cancer models that provide the prospect of more accurate scaling up of laboratory animal data to estimate human risk (70).

Risk assessment policy decisions. There are many RA policy decisions embodied in both the safety factor and the QRA approach to safety evaluations of chemical substances in food and some examples are given below. Scientific value judgements are implicit in the evaluation of nonuniform data sets and the determination of toxicological end-points on a case-by-case basis. Technical concerns may also intrude at different decision steps.

The application of safety factors to the NOEL represents a specific mechanism to address uncertainty and create conservative margins of safety proportional to the development of a "no risk" level of exposure (83). The respective values of the safety factors that are used are arbitrary and have no measured biological significance; however, the value of the safety factor chosen in a particular evaluation has a marked effect on the ADI that is set. Notwithstanding this, their appropriateness is somewhat borne out by empirical experience.

In carrying out an exposure assessment in the safety evaluation for residues of veterinary drugs, the predicted dietary intake that is used is an upper limit value, an additional safety factor affecting the final MRL. The use of an upper-bound estimate of withdrawal in the animal also incorporates a safety factor, mean exposure levels being much less (14). Choice of these statistical parameters represents a particular RA convention, and contributes to characterising exposure as a "worst case" scenario.

Comparison of potential MRLs with MRLs established from use of the veterinary drug in field trials forms the basis for recommended MRLs. If concentrations of residues lower than the potential MRLs are found in field trials, the recommended MRLs are reduced accordingly. This is an RA policy option that is unique to the evaluation of veterinary drug residues (51). In the case of pesticide residues, the MRLs are usually established at the levels resulting from use of the pesticide in accordance with Good Agricultural Practice.

Risk management. There are many situations where social benefits and economic need as well as human safety are taken into account when elaborating maximum permitted levels for chemical substances in food. It also will be apparent from the above discussion that separation of RA and RM can be difficult to achieve and the basis for RM decisions varies both between countries and within countries. In the US, cost-benefit analysis is required in risk analyses for pesticides whereas it is prohibited in risk analyses for standards for drinking water and occupational health (35). In Europe, risk analysis is the foundation of most health and safety standards but the EC Drinking Water Drirective (80/778/EEC) sets virtually zero limits for individual pesticide residues (0.01 ppb) (81). These limits bear no relationship to a toxicological risk to consumers and RM essentially constituted a political decision.

RM of contaminants and natural toxicants often embodies consideration of the food's nutritional value as well as the chemical substance's toxicity and the extent to which it can be controlled. In setting an acceptable level in food, there may be explicit consideration of the consequences of this level on the quantity and price of the food supply (33, 45, 83).

The ability to set irreducible levels for chemical substances that are based on feasibility rather than safe numerical limits (14) is an RM option (51). For contaminants, the irreducible level usually represents the concentration of a substance that cannot be eliminated from a food without discarding that food altogether. Such is the case for mycotoxins where the data does not allow "safe" numerical limits to be set (46). However it is difficult to achieve the consensus needed to develop international guidelines when maximum permitted levels are set in this manner.

The availability of analytical methods can be an important RM component in the setting of MRLs. If a practical analytical method to measure veterinary drug residues under the conditions of use is unavailable, the recommended MRLs are raised so that compliance with them can be checked.

QRA models for carcinogens in food generate a numerical estimate of risk to be used in decision-making. Legal decisions over acceptable levels of risk inevitably require accommodation between law and science (34). In recent court decisions in the US, the legal interpretation of "safe" does not mean risk-free, and "acceptable risk" involves a judgemental determination based on three factors: the statutory basis, the scientific data, and the "risks that are acceptable in the world in which we live" (34).

In Europe, there is increasing use of "unacceptable", "tolerable", and "acceptable" levels of risk in regulatory decisions (1). "Unacceptable" represents exposure that is not acceptable on any reasonable basis whereas "tolerable" represents exposures that are not welcome but can be reasonably tolerated. "Acceptable" means that exposures can be accepted without further improvement, i.e., when protection has been optimised. The Royal Society's view is that the annual fatal cancer risks per year that are represented by these terms are greater than 3×10^{-5}, between 3 and 1×10^{-5}, and 1×10^{-5} per year from a single source respectively (42).

In the Netherlands, the unacceptable level has been set at 1×10^{-6}(1). Within the "tolerable" range considered conditionally acceptable, the question remains as to what extent hazards should be reduced in the light of social and economic factors. For pesticides evaluated in the United States, the judgement is made against a negligible risk standard of less than 1×10^{-6} additional cases of cancer over

a 70-year lifetime (16). If dietary risks fall between 1×10^{-4} and 1×10^{-6}, further studies are undertaken and there may be explicit consideration of benefits.

If an RA is properly conducted, not only will exposures at or below the MRL provide the level of safety desired, but exposures at levels higher than the MRL will also provide some measure of safety (16).

Monitoring and surveillance. Establishment of maximum permitted limits for chemical substances in food involves only one aspect of a comprehensive risk analysis approach. Inclusion of monitoring and surveillance as an element of risk analysis provides a ''risk profile'' of potentially hazardous substances and a means of focusing limited analytical resources where they will have most benefit. In the case of international trade, ''risk profiles'' can only be fully utilised for risk analysis purposes if there is a complete and systematic exchange of information, coupled with continual updating of epidemiological data (26). The US Pesticide Monitoring Improvements Act of 1988 (18) mandates the Food and Drug Administration (FDA) to establish pesticide usage and other data in countries of origin of imported foods, thus adding to the information gained by analytical testing at port-of-entry.

The performance of sampling plans and analytical methods as they pertain to risk analysis of chemical substances in food is beyond the scope of this discussion. In general terms, sampling plans identify trends but are unlikely to be sufficient for prevention and are unable to cope with rapid change. Thus short-term *ad hoc* programmes may be needed to identify the presence of newly identified hazards or to establish whether small numbers of violative samples represent a significant risk. Sampling plans need to be linked to systematic traceback systems and establishment of quality assurance programmes at the point of entry of a hazard into the food chain. Rapid success in achieving a marked reduction in sulpha drug residues in bobby veal in New Zealand is a good example (13).

Accept/reject criteria. Following the detection of a violative level in an inspected ''lot'', the regulatory authority must decide on what is an appropriate action. There is a range of possible options, including outright rejection, intensified sampling of the same lot, intensified sampling of further lots or consignments of the same commodity, and recourse to monitoring data to gain more complete information on the extent of the problem (32). Decision-making criteria should be based on systematic risk analysis, particularly in the case of chemical hazards in fresh meat and meat products, e.g., the heterogeneous origin of ''lots'' should engender a different approach to the regulatory response for a single violative test than would be the case for more homogeneous commodities.

Because of widely varying levels of dietary intakes of particular foods, it is probable that some individuals in the population will exceed the ADI for a chemical substance to some extent and for some limited length of time. Quantitative data on the health risk of these incursions is generally not available but the significance of any minor incursion above the ADI can be put into context by an understanding of the scientific basis upon which the standard was established, i.e., by reference back to the animal test data and the NOEL that gave rise to the ADI for the particular substance. In this respect, the ''worst case scenario'' for exposure that has been the recent historical basis for RAs for chemical substances is under challenge (70,81) and researchers developing new RA methods are already showing that in several cases the severity of human health hazards has been overestimated (70). A systematic risk analysis approach to decision-making in the event of detection of very low numbers of violative levels of chemical substances would include consideration of the precision of the NOEL (primarily for acute toxic effects), the steepness of the dose-response curve, the likelihood of acute toxicity, the likely extent of individual exposure consequential to the violative level, and the outcome of any subsequent, intensified sampling plan over a specific period of time.

Risk analysis is necessary because imposition of specific accept/reject criteria can have major economic (and political) importance, especially in international trading situations. An important question is: what effect will the regulatory decision have on reduction of the risk? A RM option in cases of violative levels of hazardous chemicals that are the consquence of illegal use or bad agricultural practice should include a punitive response, even though a low level of violations would be unlikely to have any effect whatsoever on human health.

International activities. Risk analysis of chemical substances in meat and meat products is inevitably tied to that in all foodstuffs, and a major responsibility of the CAC is to elaborate MRLs for chemical substances in all foods. Expert groups, primarily JECFA and JMPR, consider scientific data and make recommendations on food standards on a case-by-case basis to the relevant Codex committees. The committees consider a range of ''equity and ethics'' issues as well as the recommendations from the expert groups when elaborating draft Codex standards. The consensus modality governing decision-making at a committee level contains no formal elements of RA or RM.

A number of general recommendations on the future risk analysis activities of JECFA and JMPR were developed at the 1991 FAO/WHO Food Conference (27) and these included the need to harmonise the methodology used by different countries, establishment of internationally agreed-upon principles for the RA of substances that have been shown to be carcinogenic in animal studies, and ensuring transparency of the decision-making process. The Secretariat of the Joint FAO/WHO Food Standards Programme has followed up this initiative

with the commissioning of a report on the use of risk analysis by JECFA, JMPR, and the relevant Codex committees (51).

Other wide-ranging initiatives are taking place under the auspices of the World Health Organisation, including those of the International Programme on Chemical Safety (IPCS) and the Intergovernmental Mechanism for Chemical Risk Assessment and Management that resulted from the United Nations Conference on the Environment and Development held in Rio De Janeiro in 1992 (83). The IPCS has recently begun a study on ''Guiding principles and methodology for quantitative risk assessment in setting exposure limits'' with the goal of harmonising risk analyses at the national and international level and work is also being undertaken by the Organisation for Economic Co-operation and Development to harmonise RA methodology for pesticides (58).

In the US, the EPA has sponsored a federal interagency working group to improve scientific methods of RA so as to harmonise approaches, to reduce uncertainty, and to develop an inventory of existing databases and information needs (30).

International harmonisation of MRLs is a stated objective of the CAC and this depends on reducing national differences where those differences are not justified, and mutual recognition of comparable standards employed by different countries. Nothwithstanding the above-mentioned international initiatives, work on risk analysis of accept/reject criteria for violative levels of chemical substances detected in meat and meat products at port-of-entry testing is required and this is the purvey of the newly formed Codex Committee on Import Inspection and Certification (32). Systematic exchange of information on monitoring and surveillance programmes in the country of origin will constitute an important element in this risk analysis activity.

Microbiological Hazards

Despite recognition of the problem, allocation of regulatory resources commensurate with the importance of microbiological contamination of meat and meat products is only just beginning to be addressed (7, 26, 43, 45). Control of this source of hazards has generally depended on a traditional approach, i.e., ensuring that raw materials are as free of specific hazards as possible; keeping microbiological contamination during slaughter, dressing, and processing to the lowest practicable level possible; and preventing any subsequent growth during further processing or consumer activities. HACCP programmes are specifically designed to enhance achievement of these objectives and the CAC is encouraging their use as a means to assure food safety, to better utilise inspection resources, and to provide a more timely response to problems (27). However, there has been only limited uptake of HACCP in meat production systems (52) and this is largely a consequence of the specific adaptation that is required.

Quantitative evaluation of the microbiological safety of foods has primarily been dependent on the establishment of microbiological criteria as standards, guidelines, or specifications. There is considerable debate over the application of microbiological criteria to classify food as microbiologically acceptable or unacceptable and many standards and guidelines have proven to be impractical (5, 8, 9, 39).

The principles for the establishment and application of microbiological criteria for foods include: listing of hazardous microorganisms, qualitative characterisation of likely exposure, evaluation of methods available for detection and quantification, and design of sampling plans (5, 8, 9). Any criteria that are elaborated must be effective and practical and a cost-benefit analysis should be a basic component in the development of a mandatory standard. It is apparent that application of these principles requires elements of a ''risk analysis'' approach in some form or another. Additionally, a direct and statistically based link is required between the adequacy of sampling plans and the severity of any microbiological criteria imposed (9), whereas such linkages are not currently employed with respect to MRLs for chemical substances in food. Decision criteria applied to a lot should be ''administratively and economically feasible'' and should take into account the heterogeneity of distribution of microorganisms (9).

To date it has proved impractical to elaborate microbiological criteria that adequately define the safety and wholesomeness of raw meat (8, 9). WHO has stated that the ''establishment of microbiological criteria for raw foods in general cannot serve the purpose of protecting the health of the consumer when the main source of the pathogenic microorganisms is the raw food itself, and when processing does not include steps which will eliminate or substantially reduce the numbers of these microorganisms'' (39). This is clearly the case for raw meat and meat products. The US National Research Council has similarly reviewed data on the occurrence, potential for causing infection, and pathogenicity for humans of bacterial species known to be present on chicken and has reached a parallel conclusion (15). The research committee stated that ''minimising microbial contaminants on chicken is a worthwhile objective, but it is premature to establish formal microbiological criteria for classifying raw products of poultry as microbiologically acceptable or unacceptable'' and concluded that the data required to justify such formal regulatory standards do not currently exist.

At this time, genetically engineered microorganisms are not regarded as fundamentally different to those that have been isolated from nature (and introduced into new environments) or that have been produced by breeding and selection (10); thus they have not engendered a specific RA approach.

Risk analysis. The problems associated with formal analysis of the risk of foodborne microbiological

disease are very different to risk analysis of foodborne chemical hazards.

Microorganisms multiply and die and the biological interactions are complex. In the case of meat, the characteristics of contamination during slaughter and dressing dictate the character of the initial microflora but this can be markedly modified by subsequent events. Additionally, there are marked differences in the virulence and pathogenicity of animal and environmental strains for humans, and the interaction of host and microbiological pathogen is very variable. Thus it is apparent in microbiological systems that a prediction of exposure should not lead to an automatic assumption of risk (9, 72, 76).

If an uncritical assumption is made that a human health hazard exists because of the presence of particular contaminating microflora, it would be tempting to try and characterise that risk by exposure assessment. One approach would be to construct a numerical dose-response curve for each potential pathogen that may be present in the final product and attempt to characterise risk in these terms. However, experience in ecological RA would suggest that irrespective of the difficulty in gaining the quantitative data, developing this additive organism-by-organism approach would be very difficult (71, 76, 82). In the case of meat, the biological interactions in the microflora that occur after the product leaves the slaughter- or packhouse are not able to be quantified with any certainty and as stated above, prediction of exposure should not automatically lead to an assumption of a human health risk.

Notwithstanding the problems mentioned above, microbiological hazards in food can be subjected to a formal risk analysis process, with data generally being generated from clinical and epidemiological studies in humans, and surveillance. The best probability estimates would come from a ''perfect'' epidemiological study on the human population of interest at the range of doses or exposures of interest (64). Unfortunately, such studies rarely exist. Estimates of risk derived from epidemiological studies are therefore often quantified in terms of relative risk or attributable risk.

Development of quantitative microbiological RAs is in its infancy but will probably increase in the future; this may lead to establishment of more meaningful microbiological criteria in terms of human health risks. Despite the complex challenges of microbiological risk analysis, a quantitative RA model has been developed for waterborne disease in the United States (72). This work was based on a number of dose-response relationships derived from human experiments with a range of microorganisms. A number of assumptions were made, including those of homogeneous distribution in water, average daily water intake, and an ''acceptable'' level of risk. Such work was only possible because of the low pathogenicity of the microorganisms involved and is unlikely to be repeated for other microbiological risks. Thus future microbiological RAs are likely to have a more qualitative base.

The choice of a human health endpoint is very different for microbiological hazards compared with chemical ones and this would be an important RA policy decision in a theoretical quantitative microbiological RA. Possible outcomes of microbiological contamination are true exposure, infection, disease, or death. Positive diagnostic tests in epidemiological investigations are often indicative of infection rather than disease and undifferentiated RM decisions based on an outcome that had no consequence in terms of health would be wasteful of resources that could be better used elsewhere (44, 76).

A consideration of the OIE guidelines for import risk analysis (31) provides an interesting comparison with attempts at RAs for microbiological hazards in foods. A limited number of well-documented animal diseases make up the OIE List A and List B, and adequate data on the prevalence of a specific disease in the exporting country (country factor) is usually available. Similarly, an adequate estimate of the probability of the specific disease agent being present at the time of import (country factor $\times$ animal import unit/animal product) can usually be determined. Estimation of the probability of exposure to animals or humans in the importing country and the likelihood of transmission is achieved by constructing scenario trees; this results in an unrestricted risk estimate.

Currently, RAs for microbiological hazards in fresh meat and fresh meat products are very unlikely to be able to draw on equivalent quantitative data to that described above for specific pathogens of animal health importance. The absence of detailed knowledge on the prevalence and specific zoonotic potential of the wide range of bacterial species commonly found as inadvertent contaminants on fresh meat, coupled with very limited dose-response data for those pathogenic strains known to be transmitted to humans by ingestion, makes microbiological RA for public health hazards a difficult proposition. In addition, a microbiological RA for meat at a particular time of importation/distribution is only meaningful if the subsequent measures that are taken maintain the same microbiological quality.

International activities. Current risk analysis of microbiological hazards is primarily inhibited by lack of information and lack of a detailed conceptual framework. However, these problems are not intractable and national initiatives to address these issues in the general area of food safety are underway. Several countries have recently embarked on studies to gather microbiological baseline data on dressed carcasses as a first step to provide quantitative input to a ''risk analysis'' approach to meat hygiene (43, 85). Both pathogens and indicator organisms are being investigated but these research initiatives are not expected to provide enough comprehensive data to allow development of microbiological RA models in the short term. Nevertheless, it is important that the long-term goals of this research in different countries are strategically aligned. Food safety microbiological research is both

resource-intensive and time-consuming, and information-sharing in the initial stages of the above-mentioned research would be of marked benefit. Development of a substantial conceptual framework is a prerequisite for successful microbiological risk analysis.

Development of HACCP systems for meat and meat products needs to be closely aligned with development of risk analysis methodology for microbiological hazards. A number of HACCP initiatives for raw meat appear to be based on a systematic application of traditional parameters of hygienic practice rather than a microbiological data base that validates the design of the HACCP plan. In addition, there is very little quantitative information available on the effectiveness of HACCP in reducing foodborne illness in the human population. It is assumed that operating procedures and process interventions that reduce overall microbial loads on carcasses will reduce public health risks; however, this assumption has been criticised by those who point to a general lack of correlation between total microbial counts and specific pathogens. Counter to this criticism, it should be realised that our current knowledge of microorganisms capable of causing human disease is far from complete. As an example, only about half of the human cases of presumed infectious diarrhoea are of known aetiology (76) and thus it seems reasonable to assume that a higher level of microbial contamination of gastrointestinal origin on fresh meat will result in a higher level of human exposure to potential pathogens.

In the case of slaughter and dressing, initial research in New Zealand suggest that traditional organoleptic parameters may not be related to microbial loads on carcasses and monitoring of specific CCPs in these terms could be fallacious (36). If the additive marginal risks that microbiological contamination imposes at different CCPs are to be ranked and evaluated, together with an evaluation of the cost-benefit of reducing these risks, detailed microbiological data are required. Statistical limitations of organoleptic monitoring programmes for process control in raw meat production systems also impact on the scientific validity of the HACCP plan.

Conclusions

As science advances and the regulator's ability to detect risks improves, the opportunities for influencing risks have proliferated and a desirable goal for society is to develop systematic rules for decision-making across the entire spectrum of risks (86). Within the spectrum of risk associated with foodborne hazards, regulatory authorities need to meet the challenge with quantitative, unambiguous RAs that have a transparent and readily understandable methodology.

International cooperation in food safety and harmonisation of world food regulations are essential in today's environment, but this demands resources that are only now becoming available. However, there is an enormous diversity in possible food-related hazards and therefore it is unlikely that a single risk analysis approach can be developed that will suit all situations (44,74).

In emerging as a ''regulatory science'', risk analysis offers a new opportunity to facilitate achievement of modern meat hygiene goals. International objectives in the future regulation of veterinary public health risks should include:

- Alignment of national regulatory agendas;
- Systematic exchange of information so as to establish conceptual frameworks for risk analysis;
- Development of internationally accepted RA methodology, and the opportunity for peer review;
- Development of international policy on standards of acceptable risk;
- Mutual recognition of comparable standards and specifications employed by national agencies, and reduction in those differences where risk analysis shows that those differences are not justified;
- Development of risk analysis-based principles to govern regulatory responses to violative levels of chemical substances detected in foods at port-of-entry inspection.
- Design and implementation of HACCP systems that are correlated with new developments in the field of microbiological RA.

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Policy Making in the Field of Residue Control

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Today I would like to exchange views with you about the place that residue control should take in a modern system providing health and quality assurance for meat and poultry. In doing so, I want to emphasize the governmental aspects of the subject matter, rather than go into detail on what I would call the technical aspects.

Scope of the Issue

Residue control! What's in a name? As far as residue control is concerned, there is at any rate a lot of confusion about the concept.

Residues

Let us first determine together what we understand residues to mean in the context of meat inspection. Are they just the residues and metabolites of allowed veterinary medicines and pesticides that occur in the meat of slaughtered animals? Or do they also include environmental contaminants that are found in meat?

For myself, I prefer a general definition that includes all residues of veterinary medicines, pesticides, forbidden substances, and environmental contaminants present in the meat of animals for slaughtering. But do we just restrict the concept to the residues that are found only in meat? No. Also, in this case, I adhere to the general definition. Any residues and metabolites of veterinary medicines, pesticides, forbidden substances, and environmental contaminants that can be found in the living animal, I would also rate among substances to be considered.

Control

Residue control is certainly not restricted to just residue analysis in meat. I will explain this later on. It includes all the possibilities that are at society's disposal to keep the unwanted presence of residues in animals for slaughter within acceptable standards.

By the way, this presupposes the existence of standards, a technical aspect that I shall not discuss here today. However, drawing up control programs without standards that are acceptable to all parties is a form of scrambling about that does not appeal to me very much.

Control Philosophy

Man has been eating meat for ages. The systematic inspection of meat, however, is hardly 100 years old. If I look at the origin of meat inspection, and if I consider the eminent work of von Ostertag from the previous century, I see that the finished product was only considered from the perspective of the slaughter process. That was sufficient at the time; indeed, it was not possible to do any better.

Nevertheless, the system was considered so advanced for its time and satisfied such a strong need, that for the next 100 years all subsequent legislation about meat inspection—in every remote corner of the world—was based on that principle: close inspection of the slaughter process.

During those 100 years, however, the world before, during, and after the slaughter process has thoroughly changed and has not borne a resemblance to von Ostertag's frame of reference for many decades. Yet only in the last few years has the conviction grown that meat inspection in the real world cannot just occur within the slaughterhouse. Modern assurance systems, with respect to wholesomeness and quality of products of animal origin, must be based on the control of—and information from—all links of the chain. The existing meat inspection system is so embedded, however, in legislation, education, and the way many people think, that changing it seems an almost impossible task.

For many decades we have been using all kinds of veterinary medicines and pesticides. These are mostly new substances that did not exist before, and their effect on animal, man, and environment were, and are, not always clearly known.

Only in the past 25 years has residue checking received attention. With the actual residue control

programs, we are only just at the beginning of a development. I am greatly concerned that by residue control, we will just create a model that is based strictly on examination for the presence of residues, thereby setting a large task for government and concentrating on the finished product.

That would result—and I say this without any reproach—in the making of another mistake in the history of meat inspection: a system that offers only one answer for the established shortcomings, namely, more checks by government. Residue control without a coherent philosophy means that we could easily slide down to where only a few partial interests would indicate direction. This would lead to unwanted systems—explainable in retrospect—that, by adopting rigid definition, might overestimate their own effectiveness.

A systematic approach and an adequate organization are needed to control a problem as complicated as the prevention of undesirable residues in products of animal origin. Furthermore, it is absolutely necessary, beyond question, that in this field all players of goodwill adopt a certain attitude. A residue-control system can only become truly successful if all the participants within the entire chain of animal production possess expert knowledge and a willingness to meet the agreed standards:

- Refraining from the use of substances that are forbidden.
- Permitting use only within the scope of the limitations established by law.
- Refraining from the use of substances that are superfluous.

In the final analysis, it is up to the consumer to decide what to buy. But organized consumer groups can no longer maintain a noncommittal attitude. Such important groups, which are making their voices heard everywhere—and justly so—must be taken seriously, but then assume responsibilities. I believe that, in addition to performing independent checks on guarantees from industry and government, these consumer-group responsibilities should include providing public information about the possibilities and impossibilities of animal production without the use of modern agricultural technology, and about the sense and nonsense of residue examination.

In other words, consumer organizations may be expected to help make irrational consumers into more rational buyers. Impossible expectations must not be maintained in the minds of consumers, either!

Risk analysis as point of departure in residue control.

But are those residue risks comparable to the microbiological risks of meat consumption in the previous century? What are the residues that occur today, and what risks do they involve?

First of all, internationally speaking, there has been a steep rise in the use of veterinary medicines for curative and preventive purposes. But many substances are new—and while it is true that veterinary-medicine laws have resulted in very thorough toxicological evaluations—in view of the short existence of many of these substances, not all the questions have been answered. Certainly not!

The toxicological risks for consumers from substances that have been used in cattle breeding for many years are also often not sufficiently known. The same applies to various growth stimulants. Furthermore, antibiotics are questionable due to the danger of causing allergic reactions. The real problem cases are the persistent, accumulating hydrocarbons.

Those countries that are still without very restrictive laws, or do not strictly observe such laws, find themselves in an increasingly dangerous situation. Measures taken to prevent the occurrence of heavy metals vary from one area to another. For instance, contaminations from this group of substances are not at all frequent in the Netherlands, while structurally very high concentrations of heavy metals are found in imports from certain Eastern European areas.

I conclude that the public health risks of residues in meat in 1993 are less pronounced than, for instance, public health risks associated with microbes. But consumers readily associate chemical contaminants with cancer, and therefore chemical residues are undesirable, if only for that reason.

If we consider residue control in the context of actual public health risks, as a means of protecting consumers, then there isn't really a great deal to mention: determine MRLs; establish the analytical methods; and perform a statistically sound examination of the final product. But reality has more facets. As I just mentioned, consumers have a different perception of safety than do the scientists who establish the MRLs.

Many citizens also think about animal welfare when confronted with the question whether such substances as growth stimulants, and the preventive use of veterinary medicines, are desirable in the animal production chain. Options then vary enormously about the acceptability of such use. For instance, a substance used in the illegal circuit to stimulate growth is clenbuterol. In my opinion, the effect of clenbuterol on the central nervous systems of most calves—distortion of vision, disorientation, and even spasms—is unacceptable. This is the price the living animal has to pay for an increased meat/fat content after death.

Finally, a significant group of consumers prefers meat from animals raised without unnatural additives. The use of antibiotics as a preventive, or other growth-stimulating substances, appears in a bad light. This is not related to any public-health rationale, or to any

animal-welfare rationale: call it chemophobia, if you like. But where I come from, it is a political reality that cannot be ignored.

I would like to emphasize here that residue control is indispensable, not just by reason of the possible direct risk to public health when applying undesired substances during the fattening period, but also because of the indirect risk of plummeting sales resulting from possible consumer boycotts.

You may now reply by saying: "But these indirect risks are certainly related to a lack of communication with the consumer." I think that puts it too simply.

Certain sympathies and antipathies exist in society, and we need to accept these as risk factors when selling products of animal origin. Export-oriented countries, in particular, cannot adopt the viewpoint that clients should readily accept a product whenever science has adequately established that a food product is wholesome. Clients who reject the product—for, let us say, unscientific reasons—are a real and genuine risk to producers. But a government that approaches residue risk only from the consumer's viewpoint is not justly serving and balancing the interests and rights of all its citizens: both consumers and producers alike. In saying this, I indicate that communicating risks to the citizen is one of the tasks of government.

This is done in many ways. Some politicians in Europe, however, make public any suspected presence of growth stimulants and then are later confronted with immense claims for damages. It is a political issue. In the Netherlands, the State Secretary of Public Health was recently called to give account in Parliament, since he had written that a discussion about the possible admission of natural hormones as growth stimulants in cattle should be allowed.

But how should residue risks, or their absence, be communicated to the public?

In my opinion, residue policy should be entirely open. This means, first, there should be periodic publication of residue examination results, together with information to consumers about actual residue risks.

But of equal importance is the continuous provision of public information to the producer, to clarify the dangers arising from incorrect behavior on his part: incorrect use of veterinary medicines, use of forbidden substances, careless contamination of the environment. These are patterns of behavior that, in my opinion, should be clearly regarded as socially unacceptable. By this I mean that too many producers do not view violations of these rules as wrong. Mentality must be changed first, in a way dictated by the market: A consumer who is informed about residue test results will demand only meat satisfying those standards. The producer is educated and informed to a point where he understands how to satisfy that demand. Colleagues and clients should avoid those producers not living up to the rules.

Risk-Specific Examination. Residue examination programs should be adjusted to the relative risks ensuing from the prevention of certain residues. This means that an examination program should use different ways to approach a single substance that results in different risks from one animal species to another.

How can sampling be designed to reflect the different needs of species/slaughter-class categories in relation to relative risk of residue adulteration?

Some residue programs are covertly based on two principles. On the one hand, they pretend to be monitoring programs, merely focused on checking for illegal residues to prevent their use. On the other hand, they appear to be inspection programs, leading to the need to destroy a carcass in the case of a positive finding.

In my view, the monitoring program should be just that: one that merely indicates the status of the prevention of illegal residues in the entire population. It is a tool to test the entire residue program. The results may not have consequences for the individual animal or carcass.

One possible approach that can be taken when encountering an increase in positive results is to cease monitoring and proceed with selective sampling, with the intention of taking measures for individual findings. This is what I call a specific action, specific to a certain substance, a certain animal species, a certain area, or a certain type of operation. Finally comes the need to issue a watertight guarantee for a specific unacceptably risky substance. In that case, each animal to be slaughtered will need to be examined before it can be released for consumption. Any suspected presence of illegal residues in an animal presented for slaughter, based on information or clinical and/or pathological deviations, can lead to an examination before the meat can be released for consumption.

Only by using all available information, including residue monitoring results, current veterinary medicine, and pesticide sales, and data from the enforcement authorities, can the decision be made to undertake specific actions, and to take temporary measures to examine the meat for illegal residues.

Only through adequate and responsible separation of monitoring, specific actions, and examination, will it be possible to get maximum benefit from very expensive residue programs.

The whole range of activities aimed at achieving optimum control over residues must be periodically surveyed to determine risks to man, animals, and trade, and the location of those risks. The methods that affect these risks must always be evaluated.

Similar evaluations should be made of the place where the risk is to be measured, and the measures to be taken when a standard is exceeded.

Integrated Quality Control

Currently, it often seems that one party is hiding behind the responsibility of another party. Two questions are then central: How can government and industry cooperate in the development of on-farm and preharvest residue prevention strategies? And, as I see it, the same question in other words: Can residue prevention, pathogen reduction, and meat-quality assurance be combined in one unified quality assurance program?

In the mid-seventies people in our country—as in many countries breeding cattle on an industrial scale—for the first time became closely concerned with veterinary public health, as well as with animal health and production, and began to say that the old way of meat inspection, set around 1900, was increasingly unfit.

The public grew increasingly concerned about the quality, safety, and wholesomeness of meat production; the use of veterinary drugs; the presence of environmental contaminants; and animal welfare. But also meat contamination with pathogens and toxin-producing bacteria became issues of concern.

On the other hand, the modern production of uniform fattened animals slaughtered in the great export slaughterhouses could in no way be compared to the widely varying animals once slaughtered in the public slaughterhouses.

So we tried to develop a system in which the animal food industry, the pig suppliers, the veterinary practitioners, the slaughterhouses, and the meat inspection service could work together in order to safeguard public heath and to improve the profitability of both farmer and slaughterhouse.

Therefore, in view of the continued concern about the quality and safety of meat, and the great economic importance of livestock and poultry production to the Netherlands, the Ministry of Agriculture, Nature Management and Fisheries; the Ministry of Welfare, Public Health and Cultural Affairs; and the Commodity Board for Livestock and Meat financed research projects in the eighties on what we called Integrated Quality Control (IQC) in the production of pigs, veal, and poultry. The work was mainly done within the University of Utrecht's Faculty of Veterinary Medicine.

On paper, it seems a small step to turn an Integrated Quality Control program into an Integrated Quality Assurance program. In reality it is more difficult; it is the step leading to the correct balance between the responsibilities of government, industry, and consumer.

In the IQC systems that were jointly designed by the Dutch government and industry, and which are now applied in practice, the clinical/pathological inspection aspects were the first to come to the fore.

Now it is apparent that the system is well-suited to including residue control: on the one hand, by agreements precluding use of undesirable veterinary medicines and other substances; and on the other, through sampling by interested clients in the chain to verify whether the contractual obligations of the previous links have been met.

Another form of sucessful cooperation between government and industry in our country led to the establishment of a foundation welcoming most calf fatteners, calf-milk producers, and calf slaughterhouses as members. Repeated stories about misuse of growth stimulants—forbidden in our country—almost bankrupted this sector. Now all parties concerned have concluded contracts that commit them to a rigid examination program for illegal substances. Positive findings led to severe financial sanctions—outside of court. As you would expect, positive findings from the government's residue check program for fattening calves have steeply declined since this private program started. In other sectors, too, industry, in cooperation with the Dutch government, has tried to launch comparable programs.

Actually, this type of association of producer groups is in line with Good Manufacturing Practice (GMP) codes: It is a concatenation of GMP codes for all links involved, subsequently or laterally, where tough sanctions are used to change a relatively noncommittal attitude into a code that can be enforced by the sector itself.

For countries or areas possessing an adequate infrastructure in the sector of animal production, I expect that, for the near future, producers will start to produce with ISO certifications, with a special assurance for the absence of illegal residues. Quality assurance will be audited periodically by an independent certifying institute. Sales from one link to another will only be possible between operations that can guarantee complete quality and wholesomeness of the product in this respect. Only in this way will responsibility rest where it belongs.

But systems such as this, with subsequent responsibilities for the same guarantee, can easily lead to conflicts. Here I can mention the question:

How to avoid conflicting results between on-farm and in-plant tests?

Paying more attention to on-farm residue control increases the chance for obtaining conflicting results from the on-farm examinations and the subsequent tests in the slaughterhouse.

Tests for clenbuterol in the slaughtered animal, for instance, do not appear to correlate with the results obtained from the urine and liver, as a function of time. If, for understandable reasons, only the urine

of the living animal has been tested, and, later in the slaughterhouse, for lack of urine, only the liver is sampled, then contradictory test findings can result, and, therefore, problems arise.

The problem can only be solved by always confirming positive results against blood samples, or blood serum. Another possibility is to establish contracts and stipulations of law that exclude subsequent analytical tests as serving to generate exonerating evidence against the presence of an illegal substance that was demonstrated to be present before.

However, Integrated Quality Control does not become Integrated Quality Assurance until contracts are used to concatenate and pinpoint responsibilities for production that does not meet specifications. Establishing full responsibility for incorrect deliveries is an important step toward having an industry that can bear real responsibilities in this field, i.e., the transition from control to assurance.

New Approaches in Analysis

With regard to the analytical methods to be further developed, there are some approaches that require our attention for the coming period:

Global test methods versus specific test methods

The need to develop in-line checks

Combined test methods

Global Test Methods versus Specific Methods. So far, in all residue control, the emphasis has been on chemical-analytical, biochemical, and substance-specific tests. But shouldn't we have a closer look at global methods, to use our expensive analytical methods as efficiently as possible? Should we not look at methods that tell us about the use of an entire group of substances? Often, relatively inexpensive biological tests can be used to obtain a lot of information about the use of a large group of chemically different substances.

Let me give you an example: All growth stimulants with hormonal effect have a histological effect on the prostate and Bartholin gland. Could further development of a test using this principle not lead to much less expensive testing, as compared to even more highly advanced chemical-analytical multimethods?

Another example is the extremely inexpensive microbiological test for a large range of antibiotics. Both for pre-screening of specific actions and for inspections, and within the scope of monitoring, we should pay more attention to global, group-specific test methods for the sake of efficiency in issuing guarantees.

Need for Developing In-Line Checks. Where it appears necessary to inspect individual animals, be it to demonstrate illegal substance use, or to keep meat with illegal residues from consumption, more attention will need to be paid to the development of quick and affordable tests, with rapid analysis directly after sampling. Currently, there is insufficient pressure being exerted on producers of both veterinary medicines and meat to force them to invest large sums of money into research for rapid tests. But the possibilities are vast, particularly in the field of immuno-assays. Within a short time, there will be a need for quick, affordable tests that produce reliable results directly after sampling.

Combined Test Methods. If a Dutch meat inspector decides to perform a bacteriological test, then at the same time antibiotic residue tests must be performed, as has been stipulated by law for many years. One suspicion leads to the next, of course. In our view, any serious inspector would practically always perform both tests together.

But there are also laboratory-technical developments that make it possible to perform both tests in a single analysis. In principle, with immuno-assay techniques, no distinction needs to be made any longer between the detection of substances of chemical and those with biological origins, on the condition that adequate bio-receptors are present. In the not-too-distant future, all residue tests and all microbiological tests will be made in one run.

Responsibility of Government versus Industry

There is a generally accepted rule in communication between people, and that is: Only if and insofar as someone can affect a situation, can he be held responsible. This rule applies to government, as well: Only where the government has a task can the government be held responsible. Which then are the vital governmental tasks in the field of food products of animal origin? First, let me state that the answer to such a question always depends on the place and time, but generally speaking for the civilized world, there are three tasks that governments must assume:

Developing, together with groups from society, standards for products and—if necessary—requirements for processes

Enforcing these generally accepted standards and requirements

Supervising adherence to these standards and seeing the requirements enforced

As far as residue control is concerned, it is very possible to place a major part of the tasks with the common links in the food-production chain.

No government can fail in its responsibility towards its citizens to maintain the standards set. However, the intensity of that supervision can be strongly linked to the efforts exerted by industry in the same field. The more reliable the guarantees that exist in the chain by reason of certified production and contractually agreed-upon purchase and sale, the less government supervision is required. On the whole, the result is better guarantees at reduced costs.

Every country now and in the future will have to balance the responsibility for inspection tasks between government and industry, on the basis of its own historic and social reality.

International Aspects

For many years, trade in meat and other products of animal origin between states has only been possible if the shipping state declared that the shipment fulfilled the requirements of the receiving state, by tests performed by the sending state itself. Between the normal civil trade transactions of two traders, two additional public steps were introduced. This regulation could lead to a certain—let's call it "indolence"—on the part of the exporter. Once the stamp or the export certificate of one's own government was obtained, the trader fairly quickly relinquished all sense of responsibility. Above, I clarified that responsibility should be a very important characteristic of the producer.

In the GATT and CODEX development, I foresee that we could have a trade-traffic situation where the public, long process to a guarantee will no longer be needed. Trade and production will themselves need to make the new possibilities come true. Free trade requires responsible trade partners who can be held responsible if guarantees have not been met.

If there is to be trade in product of animal origin between countries, there will need to be complete openness, and also in the field of residue control. The risk-analysis approach can only function if it is completely underwritten by producer and consumer.

Integrated Approach to Residue Control

Only an approach focused on the use of all suitable tools in due time will lead to residue control that guarantees what it is supposed to guarantee, while still remaining affordable.

The client can receive several types of guarantees of the absence of disallowed residues. For instance:

Analytical test of the final product

Analytical test at critical moments during the production process

Assurance regarding the nonuse/nonpresence of undesired substances based on reliable statements from the previous links

Assurance regarding the time of consumption of the undesirable substance and the time of excretion of the same

Certain elements need to be stressed when educating those involved in the production of cattle and meat: how to deal with veterinary medicines; one's attitude toward air, soil, and water contamination; and a conviction that illegal substances have not been declared illegal lightly.

We have before us a long road to travel if we want to raise the awareness of all links in the chain in how to deal with veterinary medicines and environmental contaminants, a road where many contributions from many parties will be welcome.

But certainties cannot only be found in the animal production chain. Even the question whether a certain substance may be produced at all, in my opinion, should be evaluated by each manufacturer against residue risks. For manufacturers of veterinary medicines, such limiting conditions as a short excretion period, availability of a simple and inexpensive analysis of the residues left in the animal or meat, and optimum information for the user should be routine. It goes without saying that the above-mentioned evaluation is made once again when approving substances for use, but then it is based on the needs of society.

Cattle-feed suppliers play essential roles in residue control: Tests of the final product guarantee that no undesirable substances enter the food chain through feed. Also required is an attitude and approach that excludes unwanted contamination.

Finally, for efficient residue control, one must search at the place and time in the entire chain where the highest concentration may be expected to occur. Monitoring programs and specific actions need to be based on that principle.

In short, residue control involves more than just residue tests: limiting conditions when developing new substances; an approval policy where residue tolerance and the suggested analytical technology are considered; permanent education of and information for all who are in any way involved in cattle and meat production; contractual guarantees in the production chain for the absence of illegal residues; sampling methods; evaluating analytical techniques; expert inspection; and penal prosecution in relation to the violations committed. All these elements can lead to adequate and affordable residue control, but only with the mutual cooperation and coordination of all responsible parties.

A program for residue control can only succeed if it is based on agreement between producer, government, and consumer; if it is flexible; and if it places responsibilities primarily on those who can actually influence the absence of undesirable residues.

Postharvest Pathogen Reduction

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Introduction

Foodborne disease should be uncommon in the western industrial countries. Public health and sanitation are generally good in these countries, and the understanding of foodborne disease, although incomplete, is well enough developed to have effective strategies in place to ensure that the food people eat will not make them ill (Bryan, 1988b; Mossel and Drake, 1990). For food properly handled and prepared, particularly in regard to cooking, there should be little risk of it containing an infective dose of a pathogenic microorganism (Flowers, 1988).

The real-world experience is quite different. Foodborne disease is a major concern in developed countries, with some evidence that the rate of food-related disease may be increasing (Todd, 1990; Cooke, 1990; Humphrey, 1991; WHO, 1991). The number of cases of foodborne illness in the USA alone has been estimated to be between 6.3 million and 81 million (Todd, 1990). The pattern of foodborne disease certainly does seem to be changing (Todd, 1990; Cooke, 1990). A number of ''new'' pathogens have emerged over the past 20 years, including *Salmonella enteritidis, Campylobacter,* entero-haemorrhagic *Escherichia coli,* and the growing importance of *Listeria* as a foodborne pathogen (Jackson, 1990; Humphrey, 1991).

The reason for the emergence of these pathogens and the increasing trend in foodborne disease is complex and not fully understood. A number of theories and explanations have been put forward (Waites and Arbuthnott, 1990; WHO, 1991). For example, *Listeria* contamination of food appears to be widespread. Although human infection is relatively rare, certain subgroups of the human population are at high risk of contracting serious disease. The fully immunocompetent person exposed to *Listeria* appears to have little or no difficulty with the bacterium (Forsyth, 1991). In immunocompromised individuals the risk of disease is much greater (Russell, 1991). The advent of AIDS, the general aging of populations in the western world, the recognition of the fatal risk with *Listeria* infection in pregnant women for the foetuses they are carrying, and the changing eating habits to more ''natural'' unprocessed foods means that *Listeria* has become of major concern to public health officials in many countries (Cox, 1989; Forsyth, 1991).

Other factors related to the persistence of foodborne disease in developed countries may be related to the production and distribution systems for food in these societies. Most people in western industrial countries lead a highly urbanised life. Their food has more than likely reached them through a long and complex chain of production and distribution. Food produced in one location may be distributed and consumed globally. Methods of modern livestock production may be having an effect on the microbial profile and diversity in food animal populations (Hunter and Izsak, 1990). The recycling of bacteria, particularly *Salmonella,* through animal feed may be an important factor promoting the distribution of pathogens in food animals (WHO, 1990).

It is estimated that maybe 97% of foodborne disease incidents derive from improper preparation and handling of the food immediately prior to consumption (Bryan, 1982; Liska, 1986). For example, a significant factor leading to the *E. coli* O157:H7 outbreak in western states of the U.S. was the insufficient cooking (time and temperature), which allowed the survival of the pathogen in the consumed hamburgers (Anon, 1993; Tuttle, 1993). Although the criticality of the handling and preparation of food

immediately prior to consumption is an undisputed control point in avoiding food-related disease, given the sometimes long and multiplex distribution and processing chain for some foods, the entry of pathogens into the chain close to the food source has the potential to put a very large disparately located population of people at risk. The cumulative chance of something going wrong at some point along a complex chain can be expected to be high. Therefore from a food regulatory point of view, the entire production and distribution chain needs to be assessed and appropriate measures implemented to control the risk of foodborne disease (farm to fork control) (Mossel and Drake, 1990).

Meatborne pathogens

Meat (red meat and poultry) is well recognised as a good medium for bacterial growth and is therefore a high risk source for foodborne disease (Ingram and Simonsen, 1980). Meat has been frequently linked to major outbreaks of foodborne disease (Roberts, 1990).

Many pathogens have been associated with meat in foodborne outbreaks, including *Salmonella* spp, *Clostridium perfringens, Staphylococcus aureus, Bacillus* spp, enteropathogenic *E. coli, Yersinia entercolitica, Campylobacter jejuni,* and *Listeria monocytogenes* (Roberts, 1990). One of the most important group of pathogens are the *Salmonella* bacteria. This group consists of over 2000 types, although a much smaller number have consistently been implicated as the cause of disease in humans. In the 1970s salmonellosis accounted for nearly 40% of all foodborne illness in the USA and Canada (Flowers, 1988). *Salmonella* bacteria are subdivided into 2 types: those that are quite host-specific pathogens, either for man or animals, and those that are promiscuous in their host range.

Salmonella

Salmonella typhi and *Salmonella paratyphi* are human pathogens and have been linked to meatborne outbreaks due to contamination of meat from infected food handlers or indirect contamination. A major food poisoning incident in Aberdeen, Scotland, in 1964 involved corned beef from South America contaminated with *S. typhi* (Waites and Arbuthnott, 1990).

It is the *Salmonella* that are nonspecific in their host range that are of greatest concern in relation to foodborne disease, because these bacteria frequently colonise the gastrointestinal tract of food animals and often contaminate the food derived from those animals, so giving rise to the potential for human disease. *Salmonella* bacteria are a major concern as a contaminant of raw poultry and red meat (Ingram and Simonsen, 1980; Roberts, 1990; Tauxe, 1991). Poultry meat is a common food source in many *Salmonella* foodborne outbreaks (Humphrey, Rowe, and Mead, 1988).

The principal zoonotic *Salmonella* type implicated in food outbreaks has been *Salmonella typhimurium* (Tauxe, 1991). In the past 20 years *Salmonella enteritidis* has emerged as a food-related pathogen of major concern (Rodrigue, Tauxe, and Rowe, 1990; Altekruse et al, 1993). Although eggs are the principal vehicle for this pathogen (Altekruse et al, 1993), poultry meat is also an important food source (Humphrey, 1991).

New serotypes can be introduced into the human population from imported meat. Threlfall et al (1992) have described how poultry meat imported from Denmark subsequently led to an upsurge in *S. berta* infections in England and Wales.

Many of the truly major outbreaks of foodborne disease have involved *Salmonella* bacteria; for example, the largest known outbreak of foodborne illness in the world involved improperly pasteurised milk in the mid-USA in 1985 in which there were 16,659 confirmed cases, and up to 197,581 suspect cases, with several deaths (Flowers, 1988; Todd, 1990). In Canada, cheddar cheese made from improperly pasteurised milk was associated with 2700 cases of salmonellosis in 1984 (Todd, 1990). There was also the *Salmonella* outbreak in Sweden in 1953-54 that resulted in the deaths of 90 people and illness in over 9,000 others, and propelled the Swedish government towards strict controls on animal production to try to control *Salmonella* in food animals. More recently, 140 *S. enteritidis* outbreaks occurred in the eastern USA between 1985 and 1989, causing 4976 cases of illness and 30 deaths; in 65 of the outbreaks shell eggs were implicated (Todd, 1990).

Recently a surge of *Salmonella* cases in Denmark has caused authorities concern. It was reported to Agra Europe of 11 June 1993 that over 80 cases of *Salmonella* infection were recorded in a 2-week period when the expected rate is 40 cases per year. Pork meat appeared to be the implicated source for the outbreak.

Improvements in slaughter hygiene for both poultry and red meat are incapable of removing totally or even greatly reducing cross-contamination by *Salmonella* (Mossel and Drake, 1988; Ingram and Simonsen, 1980). There is probably a limit to the reduction of cross-contamination achievable by improvements in slaughter hygiene (Wheleham, Hudson, and Roberts, 1986), but neglect of slaughter hygiene will make the contamination of meat carcasses much worse (Ingram and Simonsen, 1980). The best prospect for reducing *Salmonella* in raw meat is either decontamination (Mossel and Drake, 1988) or the production of *Salmonella*-free animals (WHO, 1990).

Enteropathogenic *Escherichia coli*

Meat, especially ground beef, has become a focus of particular concern because of the emergence since 1982 of a particular group of *E. coli* that produce Shiga-like toxins, which are cytotoxic to African green

monkey cells in vitro (so-called verotoxin-producing *E. coli*), of which *E. coli* O157:H7 is the exemplar (Padhye and Doyle, 1992).

This year there has been the major outbreak in the western states of the U.S. due to *E. coli* O157:H7 contamination of hamburger patties, which resulted in the deaths of 4 children and illness in over 500 people, of which about 144 required hospitalization (Anon, 1993, Tuttle, 1993). Until this outbreak, the largest single outbreak of *E. coli* O157:H7 illness had been associated with contaminated, unchlorinated municipal drinking water in which 243 people were affected (Swerdlow, 1992).

This bacterium has been responsible for a number of other outbreaks and many sporadic cases of illness (Karmali, 1989; Griffin and Tauxe, 1991). In most cases the outbreaks have been linked epidemiologically to ground beef from culled dairy cows or unpasteurised or improperly processed milk (Foster, 1986). A recent survey of cattle herds in the U.S. has shown that *E. coli* O157:H7 is present at low levels in both dairy and beef herds tested (Hancock and Holler, 1993). Milk and poultry meat have also been identified as vehicles for this pathogen (Griffin and Tauxe, 1991).

A number of 'O' and other stains of *E. coli*, other than *E. coli* O157:H7, are capable of producing verotoxins and have been isolated from patients with gastrointestinal disease (Karmali, 1989; Cheasty et al, 1992; Gunzburg et al, 1992; Burnens, 1992). Montenegro et al (1990) have isolated a number of verotoxin-producing *E. coli* from cattle sent to slaughter in Germany, and only two of the isolates were *E. coli* O157:H7. Many of the serotypes isolated by Montenegro and others were known to cause illness in humans. However, the exact role of serotypes of verotoxin-producing *E. coli* other than O157:H7 in foodborne disease is still unclear (Doyle and Padhye, 1989).

Listeria monocytogenes

Although *Listeria* is a common contaminant on fresh meat, its importance as a meatborne pathogen is on cooked and ready-to-eat meat products (Lovett and Twedt, 1988; Roberts, 1990). Proper cooking and handling will eliminate any risk of infection from *Listeria*-contaminated fresh meat. However, with contaminated ready-to-eat meat products an infective dose of *Listeria* can be consumed with the food (Roberts, 1990; Pinner et al, 1992). Processed meats and small goods present a high risk to susceptible individuals (Forsyth, 1991; Russell, 1991). For this reason, process control and storage are critical in avoiding the risk of disease. *Listeria* can grow and multiply at low temperatures often found with normal refrigeration (Cox, 1989; Forsyth, 1991; Pinner, 1992). In fact, high-risk foods such as soft cheeses, vacuum-packed smoked fish, and pate that have been kept improperly sealed in refrigerators for long periods have often been identified as the food source in sporadic cases of *Listeria* infection (Cox, 1989; Forsyth, 1991; Schuchat et al, 1992).

At the 26th Session of the Codex Committee on Food Hygiene held in Washington in March 1993 there was agreement that Hazard Analysis Critical Control Point (HACCP) is the best approach to the control of foodborne risk from listeriosis, together with consumer advice to at-risk groups in the population.

Campylobacter jejuni

Campylobacteriosis was not considered to be an important human disease in the mid-1970s, but *Campylobacter jejuni* is now probably the principal cause of foodborne enteritis in North America (Forsyth, 1988), the UK (Jones and Telford, 1991), and Australia (Powling, 1990). Poultry meat is most often implicated as the primary source of infection (Skirrow, 1990; Griffiths and Park, 1990). The nature of poultry processing and the fact the poultry processing industry may use water immersion chilling means that the poultry carcases can stay wet, which favours the preservation of the *Campylobacter* bacteria (Jones, 1991). In contrast, red meat is usually air-chilled, causing drying of the carcase surface, which is a major factor preventing the ongoing viability of the *Campylobacter*. This bacterium is more likely to survive on red meat offals and it can often be isolated from the surface of these offals tested at the point of retail sale.

Therefore, red meat offal potentially is a higher-risk source of human *Campylobacter* infection than red carcase meat (Skirrow, 1990).

In many countries the incidence of *Campylobacter* infection is higher than that for *Salmonella* (Cooke, 1990; Notermans and Hoogenboom-Verdegaal, 1992). Centers for Disease Control and Prevention epidemiologists estimate that about 1% of the US population is infected with *Campylobacter* annually, and that 50-70% of these infections are due to improper handling and preparation of poultry. Although *Campylobacter* usually causes more self-limiting disease than *Salmonella,* recently *Campylobacter* has been linked to the serious neurological disorder Guillain-Barrė Syndrome (GBS) in the US. It was reported in *Food Chemical News* of May 31, 1993, that investigators had found that 14% of GBS patients had serologic evidence of prior infection with *Campylobacter jejuni* and Japanese investigators were reported to have found 41% of GBS patients with prior infection with *C. jejuni*. If this linkage between GBS and *Campylobacter* infection is substantiated, then the public health importance of this bacterium would need to be reassessed.

Clostridium perfringens

Clostridium perfringens is a common organism found in soils and in the faeces of all animals. It can cause food poisoning in some circumstances, particularly associated with recontamination after cooking followed by improper storage (Ingram and Simonsen, 1980; Bryan, 1988b). About 40% of outbreaks where meat is the identified source involve *C. perfringens*. The minimum temperature for growth is 15° C so

proper preparation, handling, and storage should prevent infection from this organism. The bacterium usually causes illness about 8-24 hours after consumption of contaminated food (stews, roasts, gravy are often the implicated food sources). The infective dose for this bacterium is quite large (-10^6 microorganisms), and so foodborne illness usually only follows temperature abuse of cooked meat, such as holding it at 35° C to 45° C for several hours (Ingram and Simonsen, 1980).

Although *C. perfringens* vegetative cells are quite sensitive to heat, its spores are resistant. Under favourable conditions (the warmth associated with cooking) the spores will germinate and bacterial growth occur (Ingram and Simonsen, 1980).

Clostridium botulinum

Clostridium botulinum is a serious but rare cause of disease in humans. Historically, low-acid canned foods have been of particular concern and the thermal process applied to these foods is specifically designed to kill *C. botulinum* spores. The most serious risk of foodborne botulism in industrialised countries is probably from home-processed, preserved foods (Bean and Griffin, 1990; Lund, 1990) and partly processed uneviscerated fish contaminated with *C. botulinum* type E (Anon, 1992a).

In 1989 the largest recorded outbreak of botulism in the United Kingdom affected 27 people, and one person died (Lund, 1990). Disease was due to type B toxin and was associated with the consumption of hazelnut yoghurt in which the canned hazelnut conserve used to flavour the yoghurt had been insufficiently heat-treated. Meat and meat products are more likely to be contaminated with types A and B toxins. Although the risks are small, there has been a recent increase in concern due to the wider acceptance of modified atmosphere packaging for fresh meat to inhibit spoilage bacteria (Gibson and Eyles, 1989). The concern is that germination, growth, and toxin production by *C. botulinum* may occur before the overgrowth by spoilage bacteria would indicate that the product was "off."

Staphylococcus aureus

Enterotoxin-producing *Staphylococcus aureus* bacteria are commonly found on raw meat, but they do not grow well and cannot compete effectively with the other common bacteria found on meat. Therefore raw meat is not usually a vehicle for foodborne illness due to this bacterium. On processed and cooked meats where processing has eliminated or suppressed the growth of other bacteria, *S. aureus* may grow well and produce toxin. Most foodborne illness from this bacterium results from food that has been contaminated after cooking, then stored improperly at between 10° C and 37° C, providing the most favourable circumstances for growth and toxin production (Ingram and Simonsen, 1980).

Yersinia enterocolitica

Yersinia enterocolitica has been linked to human disease. Pig meat is the source most often implicated (Silliker, 1988). The bacterium causes enteritis and mesenteric lymphadentitis in man. Although considered an "emerging" pathogen, outbreaks due to this microorganism have been uncommon. The bacterium is distributed widely in the environment; however, many strains are nonpathogenic (Silliker, 1988). Like *Listeria, Y. enterocolitica* is a psychrotroph that can grow at refrigerated temperatures (0-2° C) (Roberts, 1988; Doyle, 1990).

Aeromonas spp

Aeromonads have been found in about 20% of meat and meat products sampled at retail outlets in New Zealand (Hudson and DeLacy, 1991). The role of Aeromonads in clinical human disease is still unclear (Morgan and Wood, 1988; Hudson and DeLacy, 1991).

Cryptosporidium

Cryptosporidium is a protozoan parasite that can produce diarrhoea in humans and fatality in some cases. It has become another pathogen of concern for foodborne disease (Hoskin and Wright, 1991). Human cryptosporidiosis was first reported in 1976 and has since been recognised as one of the most common gastrointestinal parasites in man (Hoskin and Wright, 1991). Although the parasite can infect immunocompetent individuals, producing a self-limiting travellers' diarrhoea in most cases, in immunodeficent people, such as those with AIDS, infection can be prolonged and life-threatening (Hoskin and Wright, 1991). *Cryptosporidia* have been isolated from a number of food animal species, including cattle, sheep, poultry, pigs, and rabbits. Waterborne infection is a major risk, especially because the oocysts of this parasite are resistant to commonly used sanitizing agents, including chlorine (Hoskin and Wright, 1991). Direct animal-to-man infection has been reported and foodborne infection through unpasteurised milk, sausage, and tripe are suspected (Hoskin and Wright, 1991).

Risk of Meatborne Disease

Bryan (1980) examined epidemiological data on foodborne diseases for the years 1968 to 1971 in the USDA and found that meat and poultry products were the identified food source in over 50% of the recorded outbreaks (year to year range 38% to 75%). This author revisited foodborne surveillance data from the USA for the years 1977 to 1984 (Bryan, 1988a). Meats were responsible for 23.2% of outbreaks, of which beef was responsible for 49% and pork 44%. Poultry was responsible for 9.8% of the outbreaks, with chicken accounting for 44.5% of these and turkey 55.5%.

Bean and Griffin (1990) collected data on foodborne diseases in the USA for the period 1973 to 1987.

These authors found that seven pathogens (*Bacillus cereus, Campylobacter* spp., *Clostridium perfringens, Salmonella* spp., *Shigella, Staphylococcus aureus,* and *Clostridium botulinum*) account for 93% of cases. Salmonella alone caused 43% of outbreaks and 51% of cases. Foodborne disease outbreaks due to Salmonella increased by 130% of cases over the period. The number of outbreaks caused by *S. enteritidis* increased about five-fold over the period.

A number of bacteria that had not previously been identified as foodborne pathogens have emerged since 1973, including *Campylobacter* spp., *Escherichia coli* O157:H7, and *Listeria monocytogenes. E. coli* O157:H7 was first identified as a foodborne pathogen in 1982 when it was linked to two food-related outbreaks of bloody diarrhoea associated with the consumption of ground beef. The emergence of this bacterium as a foodborne pathogen is of particular concern because of its propensity to attack the very young as well as the old, with the risk of haemolytic uraemic syndrome (HUS) in about 10-20% of cases and fatality in about 1-2% due to secondary complications, most often from renal failure (Spencer, 1993).

Campylobacter is the most common cause of infectious diarrhoea in many developed countries, although infections tend to be manifest as sporadic cases rather than outbreaks (Todd, 1990; Cooke, 1990). Outbreaks of foodborne disease identified with *Campylobacter* have been associated with the consumption of raw milk (Roberts, 1988; Bean and Griffin, 1990; Cooke, 1990; Skirrow, 1990). Sporadic cases have been linked primarily to the consumption of poultry (Franco, 1988; Skirrow, 1990).

Listeria monocytogenes emerged as a foodborne pathogen when it was identified as the infectious agent in three major outbreaks in the early 1980s in North America and a fourth in Switzerland. This bacterium is ubiquitous in the environment and a common contaminant of food. It presents a particular risk to certain at-risk groups in the community where it can frequently cause serious and sometimes fatal disease. The organism is also of concern because of its ability to grow at refrigerated temperatures that are used to control bacterial growth on food. A number of different foods have been associated with *Listeria* infection, including a variety of soft cheeses, coleslaw, and smallgoods.

Patterns of foodborne disease vary between countries or geographic regions. Although the pattern of foodborne disease has been similar in North America and Europe, there have been differences. For example, although *S. enteritidis* has emerged as an important foodborne pathogen on both sides of the Atlantic, in Europe phage type 4 has been of principal concern, whereas in North America it has been phage type 8 (Baird-Parker, 1990; Rodrigue et al, 1990). Eggs have been the principal food vehicle in both situations (Rodrigue et al, 1990).

In Australia, data on foodborne disease is very incomplete because public health is the entirely the responsiblity of State governments with very little role for the federal government, so national collection of statistics is somewhat ad hoc. *Campylobacter* accounted for about 43% of enteric infectious disease in 1989 (Powling, 1990). Both *Salmonella* and *Shigella* infections rose in 1989 with *S. typhimurium* phage type 9 the most common type of *Salmonella* found. *Campylobacter* and *Salmonella* are the two most important causes of enteric disease in Australia.

Bryan (1988b) reviewed the practices, procedures, and processes that have led to foodborne illness in the USA for the period 1977-1992 and compared them with data for the period 1961-1976. Factors leading to foodborne illness did not change in the two periods examined. The principal factors associated with foodborne disease were improper cooling (food stored at room temperatures or in containers that were too large during refrigeration), contaminated raw products, and inadequate heating.

Communicating Risk

Food Chemical News of 28 October 1991 reported the strategy of Mr. Tom Stenzel, executive director of the International Food Information Council, for communicating risk. Risk was defined as ''hazard + outrage'' and Stenzel suggested that any communication strategy by the food industry to explain risk to the public should concentrate on public outrage rather than numerical assessment of risk. Ten ''outrage factors'' were enumerated:

1. Is the risk voluntary?

Caffeine in soft drinks is given as example where consumer concerns were allayed once a caffeine-free alternative was made available by the manufacturer, although the vast majority of people chose to continue to drink the caffeinated variety.

2. Is the risk controllable?

The example of salt in food is given as an example.

3. Is the risk familiar?

The apparent consumer preference for the real and high risk of exposure to illness from *Salmonella*- and *Campylobacter*-contaminated poultry to the alternative small but unknown risk of eating irradiated food.

4. Is the risk visible?

The problem of acceptance of bovine somatotropin (BST) is in part related to the fact there is no way of telling if the milk being consumed is from treated cows or not.

5. Is the origin of the risk natural or artificial?

People seem to accept risks that are perceived as "natural" as opposed to those that are considered to be the result of technology, particularly in regards to chemicals in food (Ames and Gold, 1990).

6. Does the risk involve a disease like cancer, which is particularly dreaded?

7. Is the risk well understood?

8. Does the risk have catastrophic potential?

9. Do the consumers understand the benefits of the risk and feel that they receive them?

10. Are particular groups such as children especially vulnerable to the risk?

Stenzel cautioned against trying to manipulate public opinion about certain risks because of the high risk of a backlash if the public had any reason to lose confidence in the information provided to them. He suggested a number of strategies for effective risk communication:

1. Do not try to win the day on the technical argument. The acceptance or rejection of a particular risk is as much based on nontechnical criteria.

2. Avoid expert disagreement on a contentious issue if at all possible.

3. Keep the public informed about risk. Try to avoid crises. Never dismiss as trivial public concern about a certain risk.

4. Give people a choice if possible so that they feel in control of the risk.

Mosel and Drake (1990) have discussed communication of food risks in terms of the need to inform the public about processing food to enhance its safety. They suggested a 3-step procedure:

1. A report on a particular food safety issue should be prepared by a distinguished academic review body. The academic body would appoint one or two credible reviewers to undertake a critical and thorough research of the scientific literature. The reviewers would then report their findings to the academic body, which in turn would then review the findings, and after reaching a consensus, formulate its conclusions and report them in a published document.

2. The report of the expert group is reviewed by a second expert group, which is attached to and designated by the government department responsible for public health.

3. A final bulletin is issued explaining "the facts" in a simple and clear way after input and consultation with interested stakeholders.

Groth (1991) outlined the importance of risk communication in the discussion of food safety issues and the factors that must be considered in having an effective strategy to talk about risk. Each food safety issue involves both factual and value components and each is important in the discussions of controversies over public policy choices. Good epidemiological data rigorously evaluated should be the basis of the factual information of attributable causes of disease (Doll and Peto, 1981). This is equally true for foodborne disease (Bryan, 1988b, Waites and Arbuthnott, 1990). In reaching a value position on a particular risk, the choice of language used by experts to communicate risk is important for rational decision outcomes (Groth, 1991).

An important component of communicating risk is providing information to the consumer so that informed choices can be made. In this regard, issues of compulsory versus voluntary labelling of products, and the extent and nature of the information provided, has been the subject of much discussion. The Codex Alimentarius Commission General Standard for the Labelling of Prepackaged Foods recommends that product labelling should include instructions for use to ensure the correct utilization of the food (Anon, 1992b).

The Responsibility of Industry

Food processors have an economic and moral responsibility to provide their customers with safe and wholesome product. Industry also has to comply with regulatory requirements relating to a particular food commodity (Schwartz, 1991; Knowles, 1991). Food regulations are enacted by governments to protect public health and consumer interests (Schwartz, 1991). When things go wrong the likely outcome is litigation, as a number of food-related disease incidents has shown, prosecution if a food law appears to have been transgressed. In the UK changes to food safety legislation, specifically the inclusion of the due diligence clause in the 1990 Food Safety Act, has changed the way food processors view food safety (LC Food Law, May 1993).

The new act has established "due diligence" as a new principle within British hygiene law. The "due diligence" provision enables food processors to mount a defence against prosecution or litigation if the processor can prove everything reasonable was done to ensure best practices were undertaken. This defence has been used successfully a number of times already by food suppliers or manufacturers when cases were brought against them. Regulators in the UK believe the "due diligence" provision will raise standards in the food industry, because industry is now forced to take responsibility for ensuring food safety and to have a defensible position if action should be brought against them. Whether the legislation has actually resulted in safer food in the UK is open to question, but the low number of cases brought by government authorities against food manufacturers since the legislation first came into place is given as evidence that it is having the effect it was designed to do.

End-Product Handling and Cooking

End-point handling and cooking by the consumer is an important link in the chain of risk of foodborne disease. It has been estimated that 97% of foodborne illness can be traced to mishandling or preparation of food immediately prior to consumption (Liske, 1986). Therefore, applying the Pareto principle that most of the problems can be related to a small number of causes and elimination of these causes will produce the greatest improvement in outcomes, education of food handlers in restaurants and fast food outlets, and education of consumers in safe kitchen practice and food handling and preparation could be expected to yield large pay-offs in reducing foodborne illness. That this has not happened is an indication of the ineffectiveness of programs currently in place and points to the need for a greater focusing of effort on those critical operations that lead to food hazards (Bryan, 1988b).

However, it is not possible to ignore events at other points in the production and processing chain. Mossel (1988) refers to longitudinal integration of safety assurance (LISA) in which control is exercised at any point along the food chain that may cause food to become hazardous to health. Strict hygiene and sanitary control is not in itself sufficient to eliminate pathogen risk from food (Mossel and Drake, 1990). Some final "sterilizing" process is needed to make the food "safe." Traditionally this has been cooking. Food microbiology tells us that thermal destruction of bacteria is a log linear process, that is, the application of a thermal process to food of a certain intensity and duration will reduce the survivor population to some fraction of the initial bacterial load. For example, the D value is the time required to destroy 90% of organisms at a particular temperature. If the effect of the environment in which the bacteria exist during heating is ignored, the ultimate number of survivor organisms will be a function of the thermal process and the initial number of organisms present. By reducing the initial load of bacteria at the start of the thermal process, the greater will be the safety margin associated with the process itself. The same logic would apply to other processes that destroy pathogens in food. The objective of food production would be to have food available to the final preparer with a pathogen load that is as close to zero as practicable. This will expand the zone of safety around that period in the preparation process when the risk of transmitting a hazard to the consumer of the food is high.

Another issue to consider in the targeting of strategies to reduce foodborne risk is the question of minimum infective dose. The infective dose of *Clostridium perfringens* has been estimated at about 10^6 vegetative cells (Ingram and Simonsen, 1980), and for *Bacillus cereus* about 10^5 toxin-producing organisms per gram are required to produce illness (Slaten et al, 1992). Glynn and Bradley (1992) undertook a meta-analysis of published data on epidemics of typhoid and nontyphoid *Salmonella* infection. They found an association between attack rate and dose for both types of *Salmonella*, but an association between dose and disease severity only in the nontyphoid *Salmonella* outbreaks. Although the authors were able to demonstrate an epidemiological association between dose (often indirectly measured) and attack rate or case severity, it was not possible to calculate a numerical infective dose with this type of study. The exact infective dose of many pathogens is unknown. For certain pathogens, like *Salmonella, E. coli* O157:H7, *Campylobacter, and Listeria,* the infective dose may be very low in some circumstances (Roberts, 1988; Griffiths and Park, 1990; Lund, 1990, Griffin and Tauxe, 1991). In the outbreak in the western states of the USA, the contamination of the hamburger patties may have been as low as 1 to 4 organisms per gram before cooking (Anon, 1993). Therefore, the presence in food of any number of some pathogenic organisms may present a significant risk of foodborne disease.

To minimise the risk of foodborne disease, a sufficient margin of safety must be "engineered" into all stages of the food chain. This means ensuring that the level of contamination stays as low as possible. In addition, the final preparation processes should deliver a lethal effect to the residual survivor population of pathogens.

Pathogen Load on Meat

Fresh meat is a good growth medium for bacteria (Roberts, 1990). Because of its innate characteristics and the circumstances of its production, it is recognised that raw meat will always have a certain bioload on its surface unless it has been subjected to some biocidal process. There has been an absence of studies relating the health risks to humans to surface bacterial counts on carcase meat, so the significance to public health of high plate counts is unknown (Ingram and Simonsen, 1990).

For reasons of extending shelf life and also to protect consumers from high pathogen loads on meat, hygienic practices in its preparation and storage are required. Food poisoning in Germany was common in the 1930s from the consumption of raw mince meat until regulations were introduced to control its preparation and storage (Ingram and Simonsen, 1980). The traditional means of preserving meat and delaying or containing the growth of bacteria has been refrigeration. For red meat, where the most common mode of reducing meat temperature has been by air cooking, two effects operate to reduce and contain the bacterial population on the meat surface—drying, making the environment inherently more hostile for bacterial survival (reducing a_W), and cooling, which retards bacterial growth rates.

The method of slaughter and processing of poultry means that the microbial load on the raw carcase will be high (Franco, 1988; Lilliard, 1989; Bruce, 1990).

If meat cannot be sterile, is there a certain bacterial load which when exceeded is associated with a higher health risk? Is there a certain average bioload

on meat associated with processing best practices in hygienic slaughter and boning? It is not currently possible to answer these questions. In a number of countries studies currently underway will hopefully begin to provide some answers to these questions.

In the US, FSIS has its baseline study of beef with plans to extend it to other meats. Canada has also been doing work in this area (Charlebois, Trudel and Messier, 1991). In Australia, a major study has commenced into the microbiological quality of Australian beef and sheep meat. This study in some ways parallels the baseline study underway in the USA. The Australian survey is comprehensive in scope with plans to test domestic and export meat, including fully packaged meat in its variety of forms as well as carcase meat. Until good baseline data is available, it will be impossible to empirically assess whether certain interventions or practices have a positive, neutral, or even negative effect on the microbial load on meat.

Decontamination of Meat

In the previous section we said that some degree of microbial load on meat was inevitable given the nature of the product and the processes needed to convert a living animal into a food item. Most contamination of red meat is due to contamination of the carcase surface during flaying and removal of the gastrointestinal tract. While most of the microflora that ends up on the meat surface during slaughter consists of nonpathogenic spoilage organisms, a number of pathogens may also be present. Similarly during the processing of poultry, defeathering and removing of the gastrointestinal tract can cause a high level of contamination of the bird surface by pathogens such as *Salmonella, Campylobacter,* and *Listeria.*

The decontamination of food animal carcases by washes containing a variety of sanitizing agents has been reviewed by Dickson and Anderson (1992). Mossel and Drake (1990) have argued that many food products cannot be made safe for human consumption simply by attention to hygienic processing and attention to sanitary practices in the processing environment. An obvious technology that is available to apply a biocidial effect to render food wholesome and safe is irradiation (Mossel and Drake, 1990; Flowers, 1988). Although the technical arguments in favour of irradiation are strong, public acceptance of this procedure is not likely to be forthcoming in the short term. A number of other technologies are available, including the use of organic acids, trisodium phosphate, hot water flumes, and the use of hyperchlorinated rinse water (Dickson and Anders, 1992; Kenney, 1992).

Mossel (1987) has reviewed the use of irradiation for the elimination of enteropathogens on meat and poultry. A dose of about 3 kGy has been found to be effective for decomtamination without any significant deterioration of sensorial qualities of the meat. This dose of irradiation has been found to cause an overall 6 $\log_{10}$ reduction of most enteropathogens. A large amount of experimental and practical information exists to support the effectiveness and safety of food irradiation; it is a question of whether consumers can be convinced to accept this process to control foodborne pathogens (Mossel, 1987; Pszczola, 1990).

There is a body of literature to support the effectiveness of both acetic and lactic acid as decontaminants for carcase meats and offal (Dickson and Anderson, 1992). The bacteriocidal and bacteriostatic effects of these organic acids have been well documented. Smulders et al (1986) have published a comprehensive review on the use of lactic acid as a meat decontaminant.

In Australia acetic acid has been used as a decontaminating agent for lamb carcases. Eustace et al (1979) demonstrated a mean $\log_{10}$ reduction of 2 when carcases were treated with a 1.5% w/v solution of acetic acid held at 55° C with an exposure time of 10 seconds. Acetic acid has been approved by the USDA as a carcase decontaminating agent for sheep meat. This organic acid has also been evaluated on beef livers by Bill et al (1981). These authors found a mean $\log_{10}$ reduction of 1.7 for *E. coli* after immersion of the livers in acetic acid under the same treatment conditions as described previously. A drawback to the use of acetic acid in operational situations is the potential corrosive nature of the chemical on plant equipment. This effect means that special materials are required for the delivery and application systems to use this organic acid.

Although a wide range of organic acid treatment concentrations and methods have been used, there is much experimental evidence to support the effectiveness of these chemicals at concentrations (<3%) that do not compromise the sensory properties of the meat (Smulders et al, 1986; Eustace et al, 1979). In contrast to the previously mentioned evidence in support of these chemicals as meat decontaminants, the efficacy of organic acid sprays to reduce the pathogen load on beef carcases has been questioned in a recent study by Greer and Dilts (1992). These authors found that lactic and acetic acids were highly effective against spoilage organisms (2.3 to 3.5 $\log_{10}$ reductions), but were less effective against food pathogens, particularly *Salmonella typhimurium* (0.4 $\log_{10}$ reduction).

Considerable work has been done in Australia with regard to the development of a hot water decontamination cabinet (Smith and Davey, 1990). Whilst hot water applied in this manner was able to effect a 3 $\log_{10}$ reduction, the design proved impracticable for commercial purposes. After considerable modifications, a commercially viable prototype has been built, which is capable of effecting a mean $\log_{10}$ reduction of 3.3. However, to achieve this, the water has to be maintained at 80° C (Smith, 1992). This decontamination process has been evaluated for its bacteriocidal effect against a wide

range of pathogens and meat spoilage organisms, including *E. coli, Salmonella, Listeria, Pseudomonas,* and *Aeromonoas hydrophila.*

FSIS has given "interim approval" for the use of trisodium phosphate (TSP) to reduce *Salmonella* contamination of poultry carcases (*Food Chemical News,* Oct. 19, 1992). TSP can be used as a 8-12% solution at no greater than 13° C for up to 15 seconds on raw, chilled poultry. Trial data comparing 50 treated versus 50 untreated control birds had 13/50 birds positive for *Salmonella* in the control group and 0/50 birds positive in the treated group. Combined data with earlier trials showed that the *Salmonella* contamination rate declined from 17% in the control samples to less than 1% in the treated samples; *E. coli* declined from 94% to 11%. This treatment would appear to have major value in poultry processing. There are apparently plans to extend the trial work to red meat species (*Food Chemical News,* Feb. 22, 1993).

Hyperchlorinated water has been extensively studied as a decontaminant of meat carcases (Dickson and Anderson, 1992). Experimental work for this treatment does not appear to be as comprehensive as that for organic acid usage. The effectiveness of chlorine treatment seems to depend on the temperature and the pH of the rinse water, and the contact times used. To ensure continuing effectiveness of the treatment, it is essential that the free chlorine level of the rinse solution is maintained. This is particularly relevant in situations where there is a strong likelihood of contamination of the treatment water with organic matter. Treatment concentrations of chlorine have ranged from 95 ppm to 400 ppm in different studies (Dickson and Anderson, 1992). However, differences in initial microflora and experimental designs make direct comparisons of many of the reports difficult to evaluate.

HACCP vs Detection Inspection

Inspecting out defects in the final product will never ensure full safety from microbiological contamination [Microbiology and Food Safety Committee of the National Food Processors Association (MFSCNFP, 1992)]. Detection of defects in meat is based on organoleptic inspection. While this inspection may be effective in detecting visible pathology or contamination, very often the contamination by pathogenic microorganisms will not be associated with visible contamination. Therefore, in addition to regulatory inspection for visible pathology, some type of process control is needed to address the risk of microbiological contamination (NRC, 1984).

Testing for microorganisms would by necessity require some type of sampling of the product. For practical and economic reasons, it would be impossible to test the entire product. Notwithstanding the difficulties of testing meat surfaces for microorganisms, sampling inevitably means that there must be some statistical risk, dependent on the number of samples taken and the level of contamination in the product, that all tests in the sample will be negative when a particular pathogen is present at some level (Ingram and Simonsen, 1980).

End product testing in quality assurance terms is considered to be inferior to in-process monitoring to ensure a specified quality outcome (Deming, 1986). This is particularly true where microbiological quality of food is the outcome of interest. It was for this reason that the Pillsbury company developed and used the Hazard Analysis Critical Control Point system to ensure the highest safety possible for food used for American astronauts in the NASA space program. The essence of the HACCP approach is simple; it is to identify the potential hazards for a particular food related to the nature of the raw ingredients and aspects of the process of manufacture and preparation, to identify those points in the process where stringent control will result in the most likely outcome of a safe final product, to decide what type of monitoring needs to be put in place at these critical control points to ensure control is maintained, and to have a verification process to ensure that the system is operating to requirements.

HACCP is merely a tool through which hazards can be rated and controls defined (Codex Committee on Food Hygiene, 1992). The practical implementation of a HACCP system can be quite onerous and complex when there is a multitude of identified hazards, many critical control points, and no simple technical means of monitoring those control points. A failure to identify a limited number of critical control points in a HACCP system will make it too cumbersome and complex to operate effectively (MFSCNFPA, 1992).

Although HACCP applied properly should work, the question is how well can it be made to work in practice? The empirical data to answer that question is lacking. Designing experiments to provide the required answers is also problematic. Each manufacturing or processing plant tends to have a number of unique problems, making it difficult to find enough plants of comparable type to run matched controlled trials that might reasonably be expected to give useful results. Alternatively, longitudinal cross-over trials also present major problems in interpretation and evaluation. Carry-over effects from one period to the next may be large and impossible to control. The mere fact of participation in a trial may cause operational performance to improve in spite of, rather than because of, the intervention system introduced (the Hawthorne Effect). These problems of design are to some degree independent of the consideration of what outcome measures should be used to evaluate process control systems. The obvious outcome measure would be the defect rate in the final product. For food product should the outcome measure be the contamination rate for certain pathogens that may be present at very low levels, thus making detection and monitoring difficult and unreliable, or should it be an indicator organism or a composite of such organisms that are commonly

present on meat surfaces and related in some way to hygienic processing? The relationship between process control at the plant level and the rate of foodborne disease in the human population is less than clear.

For comparative studies of different processing systems, when the natural rate of contamination of a particular pathogen is very low, large trials involving a high number of samples would be required to produce meaningful results. To compare process controls, it would be necessary to control for variability on the contamination rate in animals coming to slaughter. The experimental logistics and costs of attempting such an evaluation would make the undertaking totally impractical.

The evaluation of HACCP systems of control compared to end-product inspection must be assessed on a plant-by-plant basis. Certain operating objectives should be specified based on a thorough understanding of the production process and the food microorganism ecology. The different systems need to be assessed in terms of how well they can meet these objectives. If the appropriate control variables can be determined then, statistical process control methods can be used to assess variation in the process due to assignable and random causes (Shewart, 1931). Elimination of variation due to assignable causes will improve the operation of the process, whereas improvements in the process itself are needed to improve the random variation (Deming, 1986). Therefore, statistical process control theory provides a means of assessing and evaluating the introduction of new control systems such as HACCP into the process at individual plants.

The experience of a number of individual plants with the new control system would provide cumulative assessment data for the evaluation across the meat industry on a ''best practice'' or other comparative basis.

One of the challenges that regulators face with raw food is the identification of critical control points and their validation. Many standards are based on organoleptic characteristics of the product and a possible consequence is that critical control points and procedures for measuring and validating control may also be based on organoleptic characteristics. An important task will be the commitment of sufficient resources and technical expertise to ensure rigorous scientific evaluation of HACCP. The establishment of critical limits for any process is primarily a responsibility of the team designing the HACCP program. However, critical limits must reflect regulatory standards. In Australia, quality assurance systems must address regulatory standards as minimum requirements.

HACCP and Postharvest Pathogen Reduction

At recent meetings of the Committee on Food Hygiene and the Committee on Meat Hygiene of Codex Alimentarius Commission, HACCP was endorsed as the process control system to best address the issue of food product safety. The Codex Committee on Meat Hygiene at its Seventh Session meeting in Rome in March/April 1993 suggested that HACCP under the control and supervision of the controlling authority provides a scientific approach to food safety and wholesomeness throughout the production, processing, and distribution of fresh meat. Further, the Committee recommended that HACCP, together with other quality assurance procedures, should be used wherever possible in the production of fresh meat. The HACCP systems must be developed on an individual basis by each abattoir or meat-processing establishment to address the conditions relating to the production, processing, and distribution of meat from that establishment.

The recommended guidelines for HACCP agreed to by the Codex Committee on Food Hygiene at its 26th Session in March 1993 restated the seven principles of HACCP and elaborated the 12 sequential steps for the practical application of HACCP (the Logic Sequence for Application of HACCP).

HACCP and ISO 9000

The ISO 9000 series of standards provide for generic quality systems that are applicable to any industry or economic sector (International Organisation for Standardisation, 1987). Quality assurance systems based on these standards aim to ensure product conforms to a standard that will meet the customer's required specifications. Third-party certification of the quality system following independent audit gives assurance that the documented quality system is efffectively implemented and operating so as to meet set performance criteria. The principal purpose of quality management under these systems is continuous improvement in systems and processes, leading to continuous improvement in product quality. A full ISO 9000 systems approach goes well beyond regulatory and food safety concerns in that it exposes virtually all of a company's operations to scrutiny. Companies may find it unnecessarily complex and expensive to develop such a system only for food regulatory control purposes (Merton, 1992). Likewise, regulatory authorities may find auditing of factors beyond the ambit of their responsibility unnecessary. An ISO 9000 system will only operate effectively if there is total commitment to the system by all levels of management and workers.

Whereas ISO 9000 is concerned with quality in a general sense as determined by agreement between the supplier and purchaser of the product, HACCP is concerned with quality as it relates to public health, particularly from microbiological hazards, but also for chemical and physical hazards in food. ISO 9000 series is rapidly emerging as a commercial standard in Australia. Our view is that the regulator must allow for alternative quality assurance systems. Quality systems like ISO 9000 provide a framework for a management system into which specialised disciplines such as HACCP can be integrated as a component of the quality system. The HACCP

approach is the most appropriate way to address food safety issues within quality assurance systems such as the ISO 9000 series (Codex Committee on Food Hygiene, 1993).

Mandatory HACCP

HACCP can be made a mandatory requirement for the registration of a plant to process food products. HACCP will shortly be made mandatory in Australia for all processed foods intended for export, other than processed meats. The EC is moving in that direction with its food legislation for meat products and its framework food hygiene directive (Report of 26th Session of Codex Committee on Food Hygiene). For raw and processed meat products produced for export from Australia, considerable advances have been made in the development of voluntary quality assurance programs for hygienic slaughter which incorporate HACCP principles as an optional component of these programs. The HACCP component of the programs may become mandatory in the longer term. A transition period is definitely required by industry and regulators alike. The time-frame is indeterminable and will vary substantially between companies within the meat industry. Their ability to assimilate and adopt HACCP will be largely influenced by their relative sophistication and internal cultural characteristics.

The uniform application of HACCP is a key issue for meat industry regulators (and others, including industry). This will be particularly true where accreditation for the purposes of trade between countries becomes a consideration. In this context an internationally agreed-upon framework for HACCP application, as elaborated by the Codex Committee in Food Hygiene (1993), becomes vital.

HACCP can only be made to operate effectively by the people controlling the process (MFSCNFPA, 1992). In other words, HACCP as a regulatory tool will not work if it requires government officials looking constantly over the shoulder of management and workers to ensure that a plant's operation complies with certain hygiene requirements; this is not HACCP. A HACCP system will only work effectively if the management of the plant is committed to the system, and the managers and workers see benefit in operating the plant in a way that will give them better control over the process and provide them with a higher level of confidence about the microbiological safety of the products they are producing. As in any quality system, control of the process and the resultant quality of the final product has to be made the responsibility of the people producing the product (MFSCNFPA, 1992).

HACCP Adoption by Industry

The development, implementation, and maintenance of a HACCP system will involve a major investment by food manufacturers and processors. Regulators should be encouraged to work with industry in the development of HACCP programs. Generic models can provide a guide to companies in development of their HACCP programs and we have used them in Australia. These models have their limitations, however. HACCP programs need to reflect the individual characteristics and processes of each plant. The Australian view is that the use of generic models is just one approach; the provision of advisory services is an alternative option. Our experience is that the optimal approach involves the use of a combination of measures.

Training is an essential core element for any successful HACCP program. Regulators have a clearly defined role in training in relation to the regulatory aspects, and probably a less clear role in operational aspects that may impact adversely on regulatory standards.

The Australian view is that there are a number of functions for regulators in HACCP. They include:

1. The promotion of HACCP to industry as a management system for food safety.

2. Assistance to industry in the development of HACCP programs, particularly in relation to regulatory aspects.

3. The evaluation, approval, and audit of HACCP programs.

4. The application of sanctions for nonconformity with regulatory standards.

A criticism of the breadth of this scope is that it is pervasive and shifts the focus of HACCP from an industry management system to a government compliance program.

To encourage use of HACCP in the food industry, adopters should have an opportunity to recoup their investment. The return on an investment in HACCP may be realised in a variety of ways.

In an environment of duty of care as now exists in the UK, a HACCP operation would be a strong defense against litigation. Efficiencies in the processing operation may be realised through a reduction in wastage and product rework. In addition, a HACCP program should give producers confidence to differentiate their products in the marketplace and seek a premium in price or access to a premium market on the basis of higher quality and greater assurance on safety.

The successful implementation of a HACCP program should mean a reduced requirement for direct regulatory supervision of the plant operation by government inspectors. In a user-pays environment for inspection services, the reduced inspection presence at a HACCP plant is a direct incentive for its adoption. However, it is unlikely that an investment in HACCP will be directly offset by reduced inspection charges even if regulatory inspection is at 100% cost recovery.

Better education of the public by government agencies responsible for food safety would likely translate to great consumer demand for "safer" meat. A company's best strategy to meet this demand may be through a HACCP program approved by the government agency responsible for meat hygiene and safety.

"HACCP-Based" Inspection

HACCP principles have a generality for food safety. Even if a HACCP system cannot be implemented at a meat plant, there would be advantages of having staff (both regulatory inspection staff and particularly plant staff) who have been trained in the HACCP principles, which they can use in a disciplined approach to food safety. Many operators in the meat industry will be unwilling to adopt HACCP and some will even be unable to do so, even if it were to be made mandatory. Forcing mandatory HACCP on the industry will have economic and social costs which would have to be factored into any government policy. As in any situation of change, there will be early adopters of the new system, and these people, the trailblazers, should be given every encouragement; there will also be followers who will take on the new system with some encouragement, particularly once they know that their competitors may be getting some advantage by having a HACCP system in place. Then there will be the stragglers and the recalcitrants who may skirt around and flirt with the system, but who are never able to adopt and use it properly. If HACCP is defined as the regulatory objective to achieve food safety, then obviously the implementation of the policy should be to encourage the first two groups, and to have a timetable and policy to deal with the last gorup. For both the early adopters and particularly the followers, a transition period is needed to allow them to embrace the concept of HACCP and to develop their systems. In this situation "HACCP in stages" may have some benefits. In this environment, direct regulatory supervision of operations would not be withdrawn in one go, but would be phased withdrawal. The remaining regulatory inspection could be HACCP-based so that those processes and operations associated with the highest generic risk could be the focus of inspection effort. That is, inspection activity at the plant could become "smart" rather than attempting to be universal.

For the group of operators unable to implement and sustain a HACCP system, the political decision has to be made to either regulate them out of the industry, or to have a continuation of full direct regulatory supervision of their operations, possibly using a charge base to fully reflect the true costs of providing such a service. Again, in this situation, the direct inspection presence may be HACCP-based.

HACCP can have a broader application than just that associated with regulatory parameters for food safety and regulators should exercise discretion and flexibility in this regard. In Australia, for example, regulatory requirements relating to packaging and labelling that do not relate directly to the safety of product have been successfully incorporated into quality assurance programs.

HACCP programs provide the means of directing scarce public resources towards addressing the greatest risks from meatborne disease—microbial pathogen contamination on meat surfaces that are not apparent during normal organoleptic carcase-by-carcase inspection. Risks from meatborne pathogens need to be controlled all the way through from the farm to the food on the consumer's plate. HACCP programs for slaughter floor operations are necessary, but not sufficient. HACCP must be applied to all stages of the food chain for meat: from production, through processing and distribution, and finally to preparation and handling immediately preceding consumption.

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Microbiological Criteria

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Introduction

Our food supply consists primarily of animals, plants, and products derived from them. These animals and plants are produced in association with soil, water, and air; therefore, exterior surfaces will likely be contaminated with a variety of microorganisms from these sources. Some of the microorganisms contaminating the product may be used to produce desirable changes in the food. Other microorganisms present on the product may cause quality deterioration or spoilage of the food, and some may cause foodborne disease. Successful commercial production of a food product requires control of microbiological presence and activity to achieve maximum shelf life consistent with safety of the product. Microbiological criteria can provide a tool for evaluating the acceptability of a food or process designed to control presence or growth of microorganisms. However, development and application of microbiological criteria must follow established basic principles and success will depend upon a thorough understanding of the food production process and the significance of the presence of various microorganisms.

Definitions

A microbiological criterion is a quantity upon which a judgement or decision regarding acceptability of a food or food product can be made. In most cases a criterion will specify that a certain microorganism, a group of microorganisms, or toxin produced by microorganisms be absent or limited in presence in a specified quantity of food or ingredient. A microbiological criterion should include the following information (NRC, 1985):

1. A statement describing the identity of the food or food ingredient,

2. A statement identifying the contaminant of concern,

3. The analytical method to be used for the detection, enumeration, or quantification of the contaminant of concern,

4. The sampling plan, and

5. The microbiological limits considered appropriate to the food and commensurate with the sampling plan.

Criteria may be mandatory or advisory. A mandatory criterion may not be exceeded and food that does not meet the specified limit is required to be subjected to some action, including rejection, destruction, reprocessing, or diversion. An advisory criterion permits acceptability judgements to be made, and should serve as an alert to deficiencies in processing, distribution, storage, or marketing.

Widely used types of criteria in the international food industry include standard, guideline, and specification. The following definitions were recommended in 1985 by the National Research Council's Subcommittee on Microbiological Criteria for Foods and Food Ingredients (NRC, 1985):

1. **Standard**—a microbiological criterion that is part of a law, ordinance, or administrative regulation. A standard is a mandatory criterion. Failure to comply constitutes a violation of the law, ordinance, or regulation and will be subject to the enforcement policy of the regulatory agency having jurisdiction. Microbiological standards may be useful when epidemiologic evidence indicates that a food is frequently a vehicle of disease. To be effective, the standard must attain its stated objective, namely the elimination or reduction of foodborne disease.

2. **Guideline**—a microbiological criterion often used by the food industry or a regulatory agency to monitor a manufacturing process. Guidelines function as alert mechanisms to signal whether microbiological conditions prevailing at critical control points or in the finished product are within the normal range. Hence, they are used to assess processing efficiency at critical control points and conformity with Good Manufacturing Practices. A microbiological guideline is advisory; however, management or regulatory agencies may require the conditions responsible for persistent microbiological deficiencies to be immediately corrected. Industry guidelines are often of a proprietary nature and may vary for the same product produced by different companies.

3. **Specification**—a microbiological criterion that is used as a purchase requirement whereby conformance becomes a condition of purchase between buyer and vendor of a food or ingredient. A microbiological specification may be advisory or mandatory.

Value of Setting Microbiological Criteria

With careful design and implementation, uniform microbiological criteria can ultimately enhance food safety and elevate consumer confidence in the commercially processed food supply. Microbiological criteria can equip the food industry and regulatory agencies with guidelines for control of food processing systems. In addition, uniform criteria can advance free trade through standardization of regional food quality expectations.

Purpose

Microbiological criteria may be used to assess the safety of a food and, therefore, may involve tests for specific pathogens or toxins of concern. Tests for indicator organisms may be used when a relationship between the occurrence of the indicator organism and the likely presence of a pathogen or toxin has been established. The utlimate purpose of these criteria is to protect the consumer's health.

Microbiological criteria may also be used to make decisions regarding the acceptability of products if designed to measure adherence to Good Manufacturing Practices. They can also be used to determine the appropriateness of a food or ingredient for a specific purpose. In addition, industry quality assurance programs may use criteria to monitor the potential shelf life of perishable foods.

Appropriate Criteria

Quality. The relationship between good commercial practices and quality of a food is often a question of aesthetics. In addition, microbiological quality criteria are often based upon the assumption that quality will vary inversely with numbers of microorganisms. That assumption may only be true for specific foods under a specific set of conditions. However, with sufficient background data, the following attributes of food may be measured to some extent (NRC, 1985):

1. Shelf life as perceived by specific attributes,

2. Adherence to Good Manufacturing Practices, and

3. Utility of a food or food ingredient.

Safety. Microbiological criteria designed to provide an indication of a safety of a food or food ingredient should be developed only when a potential danger can be reduced or eliminated by the application of criteria. Safety criteria are often based upon tests for indicator microorganisms whose presence suggests the possible presence of a hazard, not the presence of the hazard itself. Direct tests for pathogens or their toxins are less routinely applied.

Some raw foods are commonly contaminated with potentially dangerous microorganisms, and the presence of these organisms may be considered an inherent defect in the product. In this situation, application of microbiological safety criteria would be inappropriate. It would be unrealistic to exclude certain raw products from the food supply simply because they contain potentially dangerous microorganisms when they could be rendered safe for consumption through proper processing and cooking. For example, the extreme variability of pathogens like *Salmonella* in raw meats prevents the establishment of practical sampling plans that would ensure the absence of the pathogen with any degree of confidence. Microbiological safety criteria have less importance regarding food that must be cooked than for products that are ready to consume.

Sampling

One of the most essential components of a microbiological criterion is an effective sampling plan. To examine a food for the presence of microorganisms, either the entire lot must be examined or a representative sample should be obtained. A lot is defined as the quantity of product produced, handled, and stored within a limited time period under uniform conditions. Since it is impractical to examine the entire lot, statistical concepts of population probability and sampling must be used to determine the size of the sample from the lot and to provide conclusions drawn from the analytical results. The lot is made up of sample units, and a sufficient number of units must be selected from the lot for microbiological evaluation to determine the acceptability of a lot. The sampling plan must be designed so that it rejects inferior lots within a set level of confidence. Detailed information regarding statistical concepts of population probabilities and sampling, choice of sampling procedures, decision criteria, and practical aspects of application as applied to microorganisms in food can be found in a publication by the International Commission on Microbiological Specifications for Foods (ICMSF, 1986).

Two-class plans. A simple method for determining whether to accept or reject a food lot can be based upon a microbiological test conducted upon several randomly selected sample units (n) with a preset maximum number of sample units allowed to yield unsatisfactory results (c). The test will usually determine the presence or absence of an organism or it will determine whether samples are above or below a preset concenteration (m). Thus, in a two-class sampling plan designed to make a presence/absence decision on the lot, $n=5$, $c=2$ means that 5 sample units are obtained and examined; if more than 2 of the samples show the presence of the organism of concern, the lot is rejected.

Three-class plans. Three-class plans were designed for situations in which the quality of the product can be divided into three attribute classes based upon the concentration of the organisms within the sample units; O to *m*, *m* to *M*, and greater than *M*. The level of the test organism which is acceptable in the food is denoted by *m*. *M* is a hazardous or unacceptable level of contamination. Any count above a concentration *M* is considered unacceptable; therefore, a count from any of the *n* sample units exceeding *M* will result in rejection of the lot. In a three-class plan, *c* indicates the number of sample units that can contain a concentration above *m* but only up to and including *M*. This classification of sample units has been determined to be less than desirable, but a few of sample units (*c*) will be allowed without rejecting the lot. Thus, in a three-class sampling plan, the food lot will be rejected if any one of the sample units exceeds *M* or if the number of sample units with contamination levels from *m* to *M* exceeds *c*.

The sampling plan specified in a microbiological criterion should be appropriate to the hazard expected to be associated with the food. This expected hazard should be determined by the type of organism expected to be encountered as well as by expected handling conditions to be applied after sampling. A more stringent sampling plan should be used as the expected degree of hazard increases. Stringency is affected by the number of sample units obtained from a particular lot (*n*) and by the number of samples (*c*) allowed to be marginally acceptable or defective. ICMSF (1986) proposed a system for classification of foods according to risk into 15 hazard categories called cases with suggested appropriate sampling plans, shown below.

Plan stringency (case) in relation to degree of health hazard and conditions of use[a].

Type of hazard	Conditions in which food is expected to be handled and consumed after sampling, in the usual course of events[b]		
No direct health hazard	*Increase shelf life*	*No change*	*Reduce shelf life*
Utility (e.g., general contamination, reduced shelf life and spoilage)	**Case 1** 3-class n = 5, c = 3[c]	**Case 2** 3-class n = 5, c = 2	**Case 3** 3-class N = 5, c = 1
Health Hazard	*Reduce hazard*	*No change*	*Increase hazard*
Low, indirect (indicator)	**Case 4** 3-class n = 5, c = 3	**Case 5** 3-class n = 5, c = 2	**Case 6** 3-class n = 5, c = 1
Moderate, direct, limited spread	**Case 7** 3-class n = 5, c = 2	**Case 8** 3-class n = 5, c = 1	**Case 9** 3-class n = 10, c = 1
Moderate, direct, potentially extensive spread	**Case 10** 2-class n = 5, c = 0	**Case 11** 2-class n = 10, c = 0	**Case 12** 2-class n = 20, c = 0
Severe, direct	**Case 13** 2-class n = 15, c = 0	**Case 14** 2-class n = 30, c = 0	**Case 15** 2-class n = 60, c = 0

[a]Adapted from ICMSF (1986).

[b]More stringent plans would generally be used for sensitive foods destined for susceptible populations.

[c]n = number of sample units drawn from lot; c = maximum allowable number of positive results.

Microbiological Components and Analytical Methods

Microorganisms as components of microbiological criteria for foods include pathogenic bacteria and their toxins and indicator organisms. Adequate and practical methods must be available to detect or enumerate the microbiological component if the criteria are to be effective. Appropriate pathogenic bacteria useful as components of microbiological criteria include those that are likely to be found in the food, which then becomes a vehicle for transmission of the organism to the consumer. Suitable indicator organisms are those whose presence indicates:

1. The likelihood that pathogens or toxins may be present,

2. The likelihood that faulty practices occurred that may adversely affect safety or quality of the product, or

3. That the food or ingredient is not suitable for the intended use.

The real significance of indicator organisms as food contaminants can be understood only by having a thorough knowledge of the microflora of the production environment and the process.

Disposition of Product

The action to be taken when a microbiological criterion is exceeded depends upon the purpose for establishing the criterion. Criteria may be established for purposes ranging from acceptability of raw materials to monitoring of critical control points to acceptability of the finished product. Willingness to accept the defined appropriate action will depend heavily upon the intelligent establishment of rational and defensible criteria. Foods determined to be a direct health hazard will require cautious consideration when alternatives other than total destruction are surveyed. However, destruction of a finished product is costly, and alternative actions should be sought and used whenever possible. Reliance placed upon monitoring of critical control points to give assurance that a process has been properly applied will reduce the probability that destruction of a product will be required based upon finished product testing. Evidence that a critical control point is not under control should generate immediate action, preventing future occurrences, and may provide immediate correction of the situation before destruction or rerouting of the product is required.

Establishment and Implementation

It is not practical nor necessary to establish microbiological criteria for all foods. A microbiological criterion for a food or food ingredient should be established and implemented only when there is a recognized need and when the criterion can be shown to be effective and practical. The criterion must accomplish its objective. Additional factors to be considered include (NRC, 1985):

1. Evidence of a hazard to health based upon epidemiologic data or a hazard analysis,

2. The nature of the natural and commonly acquired microflora of the food and the ability of the food to support microbial growth,

3. The effect of processing on the microflora of the food,

4. The potential for microbial contamination and/or growth during processing, handling, storage, and distribution,

5. The category of consumers at risk,

6. The state in which the food is distributed,

7. Potential for abuse at the consumer level,

8. Spoilage potential, utility, and Good Manufacturing Practices,

9. The manner in which the food is prepared for ultimate consumption,

10. Reliability of the methods available to detect and/or quantify the microogranism or toxin of concern, and

11. The cost/benefit associated with the application of the criterion.

Cost of Implementation

Implementation of reasonable and effective microbiological criteria can provide for enhanced food safety and efficient trade. The cost of implemenation of microbiological criteria is offset by the possible reduction in foodborne disease, the reduction in finished product destruction, and the more efficient movement of products through trade channels. Cost-benefit studies are required to determine an accurate cost of implemenation and will depend on the accuracy of costs of the illness to be reduced as well as the costs of the measures to be implemented.

Application to Raw Meat and Poultry

The Codex "General Principles for the Establishment and Application of Microbiological Criteria for Foods" (Codex, 1981) state that a microbiological criterion should be established and applied only where there is a definite need and where it is both practical and likely to be effective. The presence of various pathogenic bacteria on raw meats and poultry is primarily a result of their incidence in the live animal rather than as a result of inferior hygiene. The occurrence of these pathogens in raw meat and poultry cannot be entirely prevented by the application of strict sanitary hygienic principles. In addition, the distribution of pathogens in raw products is extremely variable, severely limiting the degree of confidence of a sampling plan to indicate the absence of a particular pathogen in a lot.

Enterobacteriaceae have been frequently used in the industry as indicators of degree of hygiene during slaughter/dressing procedures. These organisms do constitute part of the raw product microflora after slaughter and dressing; however, their presence is due to unavoidable fecal contamination and they do not necessarily provide any information regarding the presence of pathogens. Even without examination for pathogens or indicator organisms, it is logical to assume, based upon the knowledge of conventional slaughter/dressing procedures, that some fecal contamination is inevitable and that pathogenic bacteria may be present on raw products. A Food and

Agricultural Organization/World Health Organization working group on microbiological criteria for foods (FAO/WHO, 1979) concluded that the number of indicator organisms in raw meat neither reflects adherence to a code of hygienic practice nor indicates presence or absence of pathogens. Therefore, criteria for raw meat and poultry products based upon indicator organisms were not considered to be justified by this group.

Microbiological quality control of meat and poultry processing involves development and use of processing methods that are designed to restrict microbial contamination and growth. Microbiological monitoring of the product and the processing environment can be used to determine the effectiveness of these procedures. Aerobic plate counts (APC) can be used to monitor these procedures and Good Manufacturing Practices, and criteria based upon such examinations are a valuable aid in establishing quality control programs. While these criteria may be effective for evaluating processing conditions in house, because of the perishable nature of the product it is probably not possible to set APC limits for criteria to be applied at the retail level or port of entry. In 1973, the state of Oregon set microbiological standards for fresh and frozen red meat at the retail level and revoked the standards four years later because:

1. The standards were unenforceable and created a general adverse reaction,

2. There was no evidence of reduction of foodborne disease or improvement in quality characteristics of the meat, and

3. The standards may have created erroneous consumer expectations of improved quality and decreased hazard.

Application to Cooked Meat and Poultry Products

Microbiological criteria can be appropriately used to evaluate the microbiological quality of raw materials, to evaluate the effectiveness of equipment sanitation, and to determine the microbiological condition of the freshly processed product. Baseline information for these evaluations must be established by the processor if useful limits are to be established. In some instances, a particular cooked product may have been determined to be a significant vehicle for foodborne disease (e.g., *Salmonella* in cooked uncured meats, *Staphylococcus aureus* enterotoxin in fermented sausages). Microbiological criteria applied at the processing plant were recommended in these situations. In most cases, application of microbiological criteria to any of these products after they have entered trade channels is of little value.

The safety and quality of commercially processed foods is primarily a result of the treatments they receive and the restriction of postprocessing recontamination. The perimeter of safety provided through traditional processing methods is very wide and greatly reduces opportunities for survival or growth of microorganisms. Control of these processes through programs such as the Hazard Analysis Critical Control Point (HACCP) system is the only logical way to assure the safety of the food supply.

Conclusions

Microbiological criteria may be used as a means of monitoring critical control points in a HACCP system. However, effective monitoring most often involves the use of physical and chemical tests as well as visual observations to confirm the successful application of a process capable of eliminating microbiological contamination. Microbiological criteria may also be used independently of HACCP to determine the ultimate acceptability of a food or process. Basic principles regarding the development and application of microbiological criteria must be followed if criteria are to meaningfully contribute to food protection.

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